

***United States Court of Appeals
for the Second Circuit***



**PETITION FOR
REHEARING**

77-4097

In The
United States Court of Appeals
For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,
THE NATIONAL ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS AND SOLGAR CO., INC., et al.,
Petitioners,

vs.

DONALD KENNEDY, Commissioner of Food and Drugs, and
UNITED STATES DEPARTMENT OF HEALTH
EDUCATION & WELFARE, Food and Drug Administration,
Respondents.

**PETITION FOR REHEARING BY THE
NATIONAL NUTRITIONAL FOODS
ASSOCIATION, THE NATIONAL
ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS and SOLGAR CO. INC.**

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U.S. COURT OF APPEALS
SECOND CIRCUIT

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TION & WELFARE, Food and Drug Administration,

Respondents.

PETITION FOR REHEARING

The National Nutritional Foods Association, The National Association of Pharmaceutical Manufacturers and Solgar Co., Inc. respectfully submit the instant petition for rehearing pursuant to the provisions of Rule 40 of the Federal Rules of Appellate Procedure. The Court is respectfully requested to grant a rehearing and reconsideration of its decision in the above-entitled case rendered on February 16, 1978.

SCOPE OF PETITION

This petition for rehearing is addressed to the ruling of this Court concerning the retention of minimum potency requirements by the Food and Drug Administration (FDA) for all dietary supplements. This issue was addressed in Point III of the principal brief for petitioners (pages 21-24), Point II, subdivision 3 of the Government's brief (pages 33-34), and pages 5-7 of petitioners' reply brief previously filed herein. The decision of this Court ruled on this aspect of the case at pages 1620-1622 of the opinion rendered herein.¹

ARGUMENT

THE AGENCY DETERMINATION THAT ANYTHING LESS THAN 50 PERCENT OF THE U.S. RDA IS WORTHLESS FOR NUTRITIONAL SUPPLEMENTATION IS CONTRARY TO SCIENTIFIC FACT AND UNSUPPORTED BY SUBSTANTIAL EVIDENCE OF RECORD

The instant request for rehearing is presented because of petitioners' concern that the ruling of this Court upholding the agency's retention of minimum potency requirements for all dietary supplements permits the establishment of a regulation which is not supported by, and is in fact contradicted by, substantial evidence of record in the administrative proceeding herein. In promulgating the regulation at issue [21 C.F.R.

¹ A copy of the opinion of this Court is set forth in the Addendum hereto.

§105.85(d)(1) and (e)(3)] (JA 100a),² the agency continued its policy of insisting that all dietary supplements contain a minimum potency level of generally 50% of the U.S. RDA. The original rationale for a similar requirement in the 1973 regulations (as understood by petitioners) was the reduction of consumer confusion.^{2a} In promulgating the most recent version of the regulations on October 19, 1976 (JA 74a-95a), the Commissioner advanced what appeared to be a new rationale for insisting on the minimum potencies at 50% of the U.S. RDA. The Commissioner explained that the purpose of retaining the minimum potency provisions was to prevent "the addition of insignificant or useless amounts" to dietary supplements. [41 F.R. 46166 (Oct. 19, 1976)] (JA 85a). In view of the lack of factual support for the new rationale, petitioners argued to this Court that the Commissioner improperly failed to develop any evidentiary basis for the proposition that anything less than 50% of the U.S. RDA is in fact "insignificant or worthless" for nutritional supplementation. (See discussion petitioners' principal brief, pp. 21-24).

In its recent decision, this Court ruled, however, that the Commissioner's minimum potency requirements had not originally been promulgated for the sole aim of avoidance of consumer

2 All "JA" references are to the Joint Appendix.

2a To this end, §401 of the Act authorizes the fixing of "reasonable" levels to create a standard of identity.

confusion. The Court found that certain findings of fact made by the Commissioner on August 2, 1973 suggested that the agency had originally intended to establish the minimum potencies for the purpose of avoiding inclusion of inadequate amounts of nutrients in dietary supplements. This Court further held that the potency limits were therefore "clearly within the language and purpose of §401." (Printed opinion p. 1622).

While this Court upheld the minimum potency requirements under the agency's authority under §401 of the statute dealing with standards of identity, it is significant to note that the Government did not rely on §401 in support of this provision. Instead, the Government's brief filed herein did not dispute petitioners' prior contention that the retention of minimum potency requirements involved a new determination by the agency.

"But that is a policy decision for the Commissioner. The law permits FDA to prescribe minimum potency requirements for dietary supplements under Sections 403(a) and 201(n) of the Act (21 U.S.C. 343(a) and 321(n))." (Government's brief p. 34)

In this regard, petitioners would respectfully note that a requirement establishing minimum potencies for all dietary supplements bears no relationship per se to the Standard of Identity provisions of §401. The current potency restrictions apply to all dietary supplements, even if they are not subject to any standard of identity under the new exemptions mandated by recent

vitamin and mineral legislation. [See §105.85(e) (3)] (JA 100a). Authority for such a provision could in fact only be based on a new finding that the inclusion of anything less than 50% of the U.S. RDA, even in a non-standardized product, would nevertheless be misleading under other sections of the law, i.e., §403(a) and 201(n) [21 U.S.C. §343(a) and 321(n)]. Not surprisingly, these were the very sections cited by the Government as authority for retaining the minimum potency requirements, thereby conceding that a new issue was presented beyond the scope of the original administrative proceeding and with respect to which no new evidence had been developed. It was for the foregoing reasons that petitioners previously requested that this Court invalidate the retention of minimum potency levels without a prior opportunity for factual support by way of notice and comment under the rulemaking provisions of the Administrative Procedure Act.

The unanticipated ruling by this Court that (despite the Government's concession) the minimum potencies could still be supported on the basis of the original findings of fact made by the agency in 1973, raises an important question for further consideration by this Court. Rulemaking in this proceeding, under §701(e) of the statute, is required to be supported by substantial evidence of record (§701(f) [21 U.S.C. §371(f)]). A review of the agency's own citations for the findings of fact cited by this Court in its opinion at page 1621, shows that these findings do not provide substantial evidence in support

of the proposition that 50% of the U.S. RDA is a level below which a given nutrient is insignificant for nutritional supplementation. In fact, the very testimony cited by the Commissioner in support of these finding demonstrates that much less than 50% of the U.S. RDA is appropriate for such purposes.

The Commissioner's findings of fact numbers 12 and 13 [38 F.R. 20735 (Aug. 2, 1973)] (JA 25a), which were cited by this Court, contain 18 transcript references as alleged support for these findings of fact. Because of the crucial nature of these citations in light of this Court's decision, these are examined below, seriatim, with a view towards analyzing their relevance to the establishment of a 50% of the U.S. RDA level below which a potency for any given nutrient is now deemed by the agency to be insignificant or worthless for nutritional supplementation.³

1. "Some Dietary Supplements Contain So Little Of A Named Nutrient As To Be Insignificant In Human Nutrition."
(First Sentence in Finding of Fact No. 12)

Will N. Swain (FDA Witness)

Mr. Swain testified that a case had once been brought by the FDA alleging that 5 mg. of potassium in a given product was of no significance to the diet (Tr. 233). This is of no relevance to the issue under consideration since there is no U.S. RDA for potassium. (See §105.85(d)(1) and (d)(4)) (JA 100a).

3 Copies of all of the relevant transcript pages are set forth in the Addendum hereto.

He further described another case brought by the FDA where it was alleged that a product did not supply adequate amounts of vitamins and minerals, but did not discuss the particular amounts which were considered to be inadequate (Tr. 488).

Dr. Arthur Grollman (FDA Witness)

Dr. Grollman testified concerning a product which contained 15 mg. of lysine (not a vitamin or mineral) which he deemed to be inadequate because the daily requirement was 1000 mg. His testimony is therefore limited in terms of a product which contained only .015% of the daily requirement (Tr. 1695-1696). Clearly, this has no relationship to a level of 50% of the U.S. RDA.

Olaf Mickelsen (FDA Witness)

Mr. Mickelsen testified concerning the nutritional insignificance of a product containing 3 mg. of vitamin C (Tr. 2448). This amount is equal to only 5% of the U.S. RDA for vitamin C. He further testified concerning a gelatin product which, in terms of amino acids (not vitamins or minerals), would provide "only one hundredth of the recommended dietary intake." (Tr. 2451) His further testimony involved a dessicated liver tablet with respect to which he could not determine the adequacy because the information was not available (Tr. 2456). Finally, he testified that 425 mg. of protein could not necessarily be considered a significant amount in human nutrition, for a given product, since only a small fraction of the product would actually be represented as essential amino acids. (Tr. 2469) Nothing in Mickelsen's

testimony even remotely relates to support of a requirement of a minimum 50% U.S. RDA level.

Robert E. Hodges (FDA Witness)

Mr. Hodges testified concerning a product which contained only 12% of the minimum daily requirement for niacin (Tr. 2935). The minimum daily requirement for niacin is 10 mg. for an adult. See former 21 C.F.R. §125.3(b)(6) (1972). This amount in the product corresponds to only 6% of the U.S. RDA.⁴ He further testified that the same product contained only 36% of the minimum daily requirement for phosphorous (Tr. 2935). The minimum daily requirement for phosphorous is 750 mg. for adults. See former 21 C.F.R. §125.4(b)(2) (1972). This amount in the product corresponds to only 27% of the U.S. RDA for phosphorous.⁵

4 U.S. RDA for niacin is 20 mg. (JA 100a).

5 The U.S. RDA for phosphorous is one gram (1000 mg.). The reference to as much as 36% of the MDR (27% U.S. RDA) is apparently a misprint. These amounts are inconsistent with the same witness's testimony that it required 16 tablets to reach the RDA (Tr. 2936). It is also inconsistent with the testimony of Dr. Sebrell, set forth below, who indicated that 25% of the U.S. RDA was the appropriate minimum level. In fact, as will be discussed later, the very regulations then proposed by the FDA which Dr. Hodges was supporting, set forth a minimum level of only 25% of the U.S. RDA. It would be inconsistent for Dr. Hodges to have testified that as much as 27% of the RDA was insignificant.

Mary E. Gullberg (FDA Witness)

Ms. Gullberg merely stated, without elaboration, that some products contained only token amounts of various B-complex vitamins and not enough calcium. (WD-G-Gullberg, Q&A 26). Clearly, this has no reference to establishment of the 50% U.S. RDA level.

2. "There is a sound scientific basis for establishing quantitative minimums on the nutrient ingredients for dietary supplements since only substantial amounts of nutrients should be represented for purposes of dietary supplementation." (Second sentence of Finding of Fact No. 12)

Victor Herbert (FDA Witness)

Dr. Herbert testified, without elaboration, that the then proposed minimum amounts were scientifically sound (Tr. 9867).⁶

Harold E. Harrison (FDA Witness)

Mr. Harrison testified only that there was a need to establish minimum levels without any further elaboration. (WD-G-Harrison Q&A 24).

John William Boehne (FDA Witness)

Mr. Boehne testified only that the mathematical basis for the minimum levels then being proposed was a numerical value equal to one-quarter of the respective maximum daily amounts, except in the case of infants where it was one-half of the maximum

⁶ As noted below, the regulations at that time sought to establish a 25% U.S. RDA level.

allowable amounts (Tr. 2764). It should be noted that at that time the maximum allowable amount was 100% of the U.S. RDA, so that the minimum discussed by this witness referred to no more than 25% of the U.S. RDA. Clearly, his testimony does not support a 50% U.S. RDA level of significance for nutritional supplementation.

Dr. William H. Sebrell (Amer. Medical Assn. Witness)

Dr. Sebrell, previously described by this Court as a major witness in the proceeding,⁷ testified that vitamin supplements should contain a minimum potency level (WD-3A-Sebrell, Q&A 26). He further testified that the minimum should be 25% of the RDA, except in the case of infants where it should be set at 50%. (Q&A 27). With respect to minerals, he also testified, without elaboration that a minimum level would be appropriate (Q&A 39). Clearly, Dr. Sebrell's testimony does not support and, in fact contradicts, the agency's attempt to establish a 50% U.S. RDA level of significance for nutritional supplementation.⁸

7 See NNFA v. FDA, 504 F.2d 761 at 792-799 (2d Cir. 1974).

8 If anything, substantial evidence of record suggests that 25% of the U.S. RDA is appropriate as minimum level. Petitioners, however, do not accept this as conclusive, particularly in light of the fact that no opportunity for cross-examination of Dr. Sebrell was available. See NNFA v. FDA, supra. The balance of the testimony suggests that the other witnesses were concerned with inadequate levels which in almost all cases were significantly less than 10% of the U.S. RDA.

3. "Certain dietary supplements are objectionable because they must be taken in large numbers of units for the user to get the designated amounts of the nutrients involved." (First sentence of Finding of Fact No. 13)

Dr. Arthur Grollman (FDA Witness)

Dr. Grollman objected to a product which required the ingestion of 9 tablets daily (Tr. 1685). He also discussed a product containing 16% of the minimum daily requirement for calcium (Tr. 1685). The minimum daily requirement for calcium is 750 mg. for an adult. See the former 21 C.F.R. §125.4(b)(1) (1972). This amount in the product corresponded to only 12% of the U.S. RDA for calcium.⁹

Robert E. Hodges (FDA Witness)

Mr. Hodges testified concerning a product which required 16 tablets to provide the daily amount of the RDA (Tr. 2936). Accordingly, each tablet contained only approximately 6% of the RDA. Clearly, his testimony has no relationship to the establishment of 50% of the U.S. RDA as a level of significance for nutritional supplementation.

4. "In establishing a standard of identity for dietary supplements it is medically and pharmacologically sound to establish a standard of identity for dietary supplements on the basis of units suitable for and practical of consumption in one day." (Second sentence of Finding of Fact No. 13)

Dr. Arthur Grollman (FDA Witness)

Dr. Grollman testified only that dietary supplements should

⁹ U.S. RDA for calcium is 1 gm. (1000 mg) (JA 100a).

contain units suitable for consumption in one day (Tr. 1661), which is not directly relevant to the issue at hand.

Robert E. Hodges (FDA Witness)

Mr. Hodges testified only that labeling information should be expressed in terms of daily quantity because that was the "universally accepted way." (Tr. 2956) This, too, is not directly relevant to the issue at hand.

Analysis of the foregoing testimony supporting the findings of fact cited by this Court in its opinion, reveals a complete lack of evidentiary support for the establishment of 50% of the U.S. RDA as a general level below which potencies of vitamins and minerals are not significant for nutritional supplementation. As further noted, the testimony of Dr. Sebrell (WD-3A-Sebrell, Q&A 27) clearly showed (in the only testimony which squarely addressed this issue) that in his view the minimum level should be 25% of the RDA.

The above gap between the agency's establishment of a 50% U.S. RDA level and the contradictory testimony at the hearings, arises from the fact that the agency's own proposal being considered at the hearing and in support of which all of the aforementioned witnesses testified, itself provided for a general minimum level of only 25% of the U.S. RDA. See 31 F.R. 15731-15732 (Dec. 14, 1966) set forth in the Addendum hereto. For example, the U.S. RDA for vitamin A is 5000 units. The current minimum level (lower limit) for adults in the regulations before

the Court is 50% of the U.S. RDA, i.e., 2500 units (JA 100a). Yet, the agency's own proposal, with respect to which the entire administrative hearing was addressed, listed the minimum amount of vitamin A (except for infants) at only 1250 units, i.e., 25% of the U.S. RDA. See 31 F.R. 15731-table 1 set forth in the Addendum hereto.

The simple truth is that the agency's selection of a 50% U.S. RDA level was not based on any evidence adduced at the hearing, but instead was unilaterally introduced for the first time on January 19, 1973. See 38 F.R. 2158 (JA 7a). At that time, the agency unilaterally increased the proposed maximum potency levels to 150% of the U.S. RDA¹⁰ and also raised the minimum level to 50% of the U.S. RDA for the first time. No findings of fact or transcript references were cited by the agency in support of this move, and obviously there could be none.

Support for these unilateral agency moves could only be based on an alleged right of the agency to arbitrarily "draw a line" at 50% of the U.S. RDA and that, in fact, is precisely what the Government has claimed on the instant appeal. (Government's brief, p. 34). In this respect, the new vitamin and mineral legislation drastically alters the validity of the agency's position. While the arbitrary drawing of a line might be appropriate, and in fact was upheld by this Court for the purpose of reducing consumer confusion, this Court has already noted that this primary

¹⁰ The previous maximum had been 100% U.S. RDA.

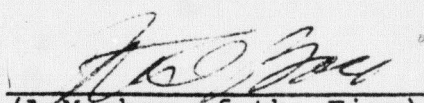
purpose of the original regulations has been invalidated by the new vitamin and mineral legislation. Now, the agency's new or modified rationale is only that a minimum level is necessary to prevent the inclusion of insignificant amounts of nutrients. Surely, an agency cannot be permitted to arbitrarily decide that anything less than 50% of the U.S. RDA is insignificant in the absence of any evidence and in the face of express contradictory testimony in the record, as discussed above. The retention of such provisions in light of the drastic change of circumstances was, therefore, inappropriate.

In light of the foregoing, and in the interest of insuring scientific accuracy for the important regulations in this proceeding, it is respectfully requested that the instant petition for a rehearing and reconsideration be granted and that, upon such rehearing, this Court's opinion dated February 16, 1978, be modified to the extent of including within the remand to the agency a requirement that the agency develop factual evidence to support the retention of minimum potency requirements for dietary supplements.

Dated; New York, New York
March 2, 1978

Respectfully submitted,

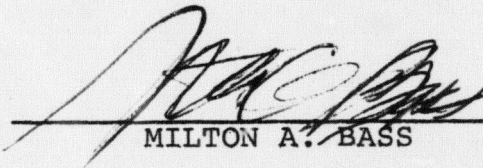
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CERTIFICATE

The undersigned counsel for The National Nutritional Foods Association, The National Association of Pharmaceutical Manufacturers and Solgar Co., Inc. respectfully certifies that the foregoing petition for rehearing is not frivolous and is presented in good faith and not for delay.


MILTON A. BASS

ADDENDUM PAGE 1

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Nos. 604, 605—September Term, 1977.

(Argued December 7, 1977 Decided February 16, 1978.)

Docket Nos. 77-4097, 77-4104

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,
THE NATIONAL ASSOCIATION OF PHARMACEUTICAL
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UNITED STATES DEPARTMENT OF HEALTH, EDUCATION &
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Respondents.

MILES H. ROBINSON, *pro se*,

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v.

DONALD KENNEDY, Commissioner of Food and Drugs, and
UNITED STATES DEPARTMENT OF HEALTH, EDUCATION &
WELFARE, Food and Drug Administration,

Respondents.

Before:

FRIENDLY, SMITH and MESKILL,

Circuit Judges.

ADDENDUM PAGE 2

Petitions to review revised orders of the Food and Drug Administration establishing a standard of identity and labelling requirements for vitamins and minerals.

Regulations vacated and cause remanded.

MILTON A. BASS, Esq., New York, N.Y. (Jacob Lauffer, Esq., and Bass, Ullman & Lustigman, Esqs., New York, N.Y., of Counsel), *for Petitioners, The National Nutritional Foods Association, The National Association of Pharmaceutical Manufacturers and Solgar Co., Inc.*

MILES H. ROBINSON, M.D., Potomac, Md., *Petitioner pro se.*

CHARLES R. MCCONACHIE, Chief, Consumer Affairs Section, United States Department of Justice, Washington, D.C. and JESS H. STRIBLING, Esq., Food and Drug Administration, Rockville, Md. (John H. Shenefield, Assistant Attorney General, Antitrust Division, Department of Justice, Washington, D.C., and Stephen H. McNamara, Acting Chief Counsel, Food and Drug Administration, Rockville, Md., of Counsel), *for Respondents.*

FRIENDLY, *Circuit Judge:*

This is the latest but, unfortunately, probably not the last chapter in the bitter battle between the Food and Drug Administration (FDA) and manufacturers and vendors of pills and liquids containing vitamins and minerals and citizens allied with the latter. While the manufacturers and

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vendors have obvious private interests as well, the battle reflects what appears to be a sincere sentiment on the part of many citizens that daily ingestion of a substantial quantity and variety of vitamins and minerals in the form of pills or liquids, in addition to those furnished by ordinary diet, is needed for good health, especially because of the increasing consumption of "the modern food fads—sweet drinks, junk foods, heavy sugar diets" and "wheat germ-free bread and nutritionally inadequate breakfast foods," 121 Cong. Rec. S. 21856 (daily ed. Dec. 11, 1975) (Sen. Proxmire), and the FDA's equally sincere belief that the promotion of what, on a previous review, this court called a "dazzling array" of recommended daily dosages and combinations, 504 F.2d at 776, is causing consumers to waste millions of dollars annually in the purchase of vitamin and mineral preparations which they either do not need at all or do not need in the potencies or combinations that are being bought. The battle began nearly a generation ago with the FDA's publication of a Proposal to Revise Regulations in the Federal Register of June 20, 1962, 27 F.R. 5815; the proposal included the establishment of standards of identity for "food for special dietary uses" and revised label standards for them. Because the FDA's establishment of a standard of identity under § 401¹ of its prescription of labels for foods for special dietary use under § 403(j) is among the few instances on the statute books where an evidentiary hearing is required for rule-making, § 701(e), over twenty-two months were devoted to such a hearing, which developed a transcript of 32,405 pages and hundred of exhibits. The Commissioner published final regulations on August 2, 1973, 38 F.R. 20708-18, 20730-40.

¹ All section references to the Federal Food, Drug and Cosmetic Act in this opinion are to the Act itself and not to 21 U.S.C. §§ 301, *et seq.*

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Fifteen petitions to review were filed; their disposition by this court required a 47-page opinion, 504 F.2d 761 (1974), *cert. denied*, 420 U.S. 946 (1975), familiarity with which is assumed. Although "broadly sustaining the regulations," 504 F.2d at 786, we stayed them and remanded the case to the FDA to carry out a number of directives. One of them was that it should modify § 80.1(b)(4) of the Standard of Identity regulations to include increases in upper limits of potency as well as new combinations of vitamins and minerals and to entertain applications thereunder before the new regulations became effective, 504 F.2d at 783-86. We invalidated § 125.1(c) of the Label Regulations, which forbade the inclusion in "general purpose foods or dietary supplements of vitamins and minerals" of two vitamins² and six minerals,³ which the FDA had recognized to be essential to human nutrition but for which no U.S. RDA's (recommended daily allowances) had been established, 504 F.2d at 786-787,⁴ and § 125.1(h) of the Label Regulations declaring that preparations containing more than the upper limits of the U.S. RDA per serving were "drugs." 504 F.2d at 788-89. Finding that the cross-examination of Dr. William Sebrell, the most knowledgeable witness testifying on the preparation of the 1968 National Academy of Science RDA's whence the U.S. RDA's were drawn, by Dr. Miles Robinson, then representing the National Health Federation and now a pro se petitioner

2 To wit, vitamin K and choline.

3 To wit, chlorine, fluorine, manganese, potassium, sodium, and sulfur. See 38 F.R. 20717 (§ 125.1(c)). Since then, the minerals chromium, molybdenum, nickel, selenium, silicon, tin, and vanadium have been added to the list while sulfur has been removed from it. See 21 C.F.R. §§ 105.3(c), 105.85(d)(4).

4 We took a similar view with respect to any nutrients recognized as essential in human nutrition but not mentioned anywhere in the regulations, see 504 F.2d at 787, n. 31.

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here, had been improperly restricted by the hearing examiner, we instructed the FDA "to reopen the record for the limited purpose of permitting reasonable cross-examination of Dr. Sebrell (or, if he is not available, some other qualified member of the [Food and Nutrition] Board [of the National Academy of Sciences-National Research Council] by Dr. Robinson or counsel of some other similarly interested Participants," 504 F.2d at 792-99. We faulted § 125.2 (b)(2) of the Label Regulations as unsupported by substantial evidence insofar as it prohibited claims that a balanced diet of ordinary foods would not supply an amount of iron adequate for women of childbearing age and for children; as to this we directed that the FDA either supply further evidence to justify this prohibition or to "insert a proper qualification" in the regulation, 504 F.2d at 802. Finally, we directed that fresh fruits and vegetables be exempted from the regulations, 504 F.2d at 806-07.

After the Supreme Court had denied petitions for certiorari by those who had been petitioners here, 420 U.S. 946 (1975), the Commissioner published in the Federal Register of May 28, 1975, 40 F.R. 23244-50, a paper bearing the three-headed title "Opportunity for Filing Applications for Additional Formulations of Dietary Supplements of Vitamins and Minerals; Preliminary Notice of Reopening of Hearing; Tentative Amendments to Final Orders." Under the first heading the FDA prescribed how and where applications for additional approved formulations should be made; it also advised that it would not be necessary to seek approval of products having a higher potency than the U.S. RDA's so long as the products consisted of a single vitamin or mineral since the Commissioner intended to amend the regulations to permit this. Under the second heading the Commissioner proposed to tender on the reopened hearing, in lieu of

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Dr. Sebrell who was no longer a member of the Food and Nutrition Board, his successor as Chairman, Dr. Alfred E. Harper. The cross-examination was to include (1) the methodology employed in development of the recommended dietary allowances by the Board and the scientific foundation upon which these allowances are based, (2) the scientific appropriateness of the Food and Drug Administration's use of the Board's recommended dietary allowances, and (3) possible biases or conflicts of interests on the part of the Board, as well as other relevant subjects, and the FDA intended to open cross-examination not only to Dr. Robinson but "to as many participants reflecting as many points of view as is reasonably possible." 40 F.R. 23245. Under the third heading the Commissioner proposed a number of amendments to the regulations, most of which were intended to implement this court's order.

The reopened hearing before an Administrative Law Judge (ALJ) occurred in November, 1975, lasted six days and produced an additional 1119 pages of transcript. On February 20, 1976, the ALJ entered a report and recommended order finding that:

(1) Alleged biases and/or conflicts of interest of the witness or other members of the Food and Nutrition Board have not been established in any degree which might reasonably be interpreted as affecting the judgment of the witness or other members of the Board in determining the RDA's.

(2) Although the Board determined the RDA's as a guide to sound nutrition for a healthy population, and not as standards for regulatory purposes, there is nothing inconsistent or unsound in using the RDA's as a basis for regulatory determinations as to labeling and nutritional content requirements, and

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(3) Information adduced through detailed cross-examination into the scientific basis and methodology utilized by the Board in determining the RDA's does not require adoption of regulations differing from those published.

Exceptions to this were filed.

Meanwhile the scene of action had shifted. On April 22, 1976, the President signed Public Law 94-278, extensively amending the Food, Drug and Cosmetic Act. Section 501(a) added to the Act §411, which we reproduce in the margin.⁵

5 (a) (1) except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

(b) (1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i) (2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) (A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competi-

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Broadly speaking subsection (a) put an end to the FDA's efforts to limit the potency of any vitamin or mineral included in "a food for special dietary use," as defined in subsection (c), or the number or combination of vitamins, minerals or other food ingredients included therein except

tion, exemptions shall be established by regulations promulgated by the Secretary.

(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

- (i) vitamins,
- (ii) minerals,
- (iii) represented as a source of vitamins or minerals.

(c) (1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, or liquid form, or

(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1) (B) (i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 403(j) insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

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when the vitamin, mineral, other ingredient of food, or food, . . . is represented for use by (1) individuals in the treatment or management of specific diseases or disorders, (2) children under the age of twelve, or (3) pregnant or lactating women. The limitation of the FDA's authority with respect to labelling was much less severe; the main thrust was to forbid FDA regulations that would wholly prohibit inclusion in labels of ingredients which were not vitamins or minerals. Section 501(b), which is of special importance to our decision, provided:

The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

Without engaging in any further proceeding, the Commissioner published final regulations in the Federal Register of October 19, 1976, 41 F.R. 46156-76. The Commissioner believed that almost all the applications for new formulations had been mooted by the 1976 amendment. He approved a new combination of vitamin A, D and C with provision for optional inclusion of vitamin E and/or iron, as a dietary supplement for infants and young children, denied an application for a preparation containing a higher level of vitamin B₆ for pregnant and lactating women, and determined to treat as drugs multivitamin supplements for women taking oral contraceptives which contained estrogen. He overruled the exceptions to the ALJ's report concerning the examination of Dr. Harper, to other evidentiary rulings at the reopened hearing, and to FDA's continued reliance on the NAS-RDA's. He passed upon and largely rejected the exceptions to the amendments proposed in the notice

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of May 28, 1975, noting that many exceptions were mooted as a result of the 1976 legislation. The Commissioner's technique was essentially to readopt the 1973 regulations with reorganization "to improve clarity," modifications designed to meet our directions, addition of a section classifying dietary supplements not "generally recognized as safe" as "food additives," and a further modification, § 80.1(e), "which provides that products subject to the new vitamin/mineral legislation are not subject to the maximum potency limits and the limits on inclusion of ingredients otherwise imposed on dietary supplements by §§ 80.1 and 125.2 (b)(5)." 41 F.R. 46170.

This action by the Commissioner evoked an "urgent petition" dated November 30, 1976 by the attorneys for National Nutritional Foods Association, National Association of Pharmaceutical Manufacturers and Solgar Co., Inc., who constitute one group of petitioners on this second round of review. While the petition advised that the details of the new regulations were being evaluated, its emphasis was directed at the FDA's procedure in promulgating the final regulations without having "requested from the public any input as to what changes would be necessary in the regulations in light of the newly enacted vitamin and mineral legislation." The petition asked the Commissioner to "withdraw the final order published in Federal Register of October 19, 1976 and substitute therefor a republished proposed order which gives the public the full right to submit comments and objections in accordance with the requirements of § 701(e) of the Federal Food, Drug and Cosmetic Act." A prompt ruling was requested.

The Commissioner made no answer for four and a half months.⁶ In the Federal Register for April 19, 1977, 42

⁶ Meanwhile the regulations had been recodified into 21 C.F.R. Part 105, with § 105.3 containing definitions, §§ 105.77 and .79 containing labelling requirements and § 105.85 the standard of identity.

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F.R. 20292-96, he published his response to the petition of November 30, 1976, as well as to a letter dated November 12, 1976, in which Dr. Robinson expressed disagreement with the FDA's ruling that the cross-examination of Dr. Harper had not impugned the U.S. RDA's. On the procedural issue, the Commissioner now took note of § 501(b) of the 1976 legislation, as he had not previously done. He concluded that he was nevertheless empowered to issue final regulations "without prior notice of proposed rulemaking and public procedure" because of the provision in 5 U.S.C. § 553(b) that "except when notice of hearing is required by statute," the requirement of publishing notice of proposed rulemaking does not apply

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

The Commissioner reviewed the provisions of the final regulation "that were prompted by the new legislation," and concluded in each case that public rulemaking procedures would be "impracticable" and "unnecessary" because he was simply bowing to the will of the legislature.⁷ The Commissioner further rejected the contention that he should have followed the "hearing on the record" proce-

⁷ The Commissioner altered a provision of the regulations that would have required a vitamin and mineral preparation "newly authorized by Congress" to "bear a term that is accurately descriptive of its vitamin and/or mineral composition" so as to say simply that such product shall bear as part of its name "an appropriately descriptive term." The Commissioner left intact a provision requiring that such a product "accurately identify the group for which it is offered," finding the requirement "obviously reasonable." See 42 F.R. 20295.

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dure described in § 701(e). These petitions for review followed.⁸

Discussion

(1) The procedural questions.

We conclude that the Commissioner committed procedural error and that this requires a further remand. We reach this conclusion with regret in light of the fifteen and a half years that have elapsed since the FDA began its efforts to achieve better control of the identity and labelling of vitamin and mineral preparations. However, we are convinced that in failing to give notice of proposed rulemaking and to accord an opportunity for public participation in the process, as provided in 5 U.S.C. § 553(b) and (c), the Commissioner violated the mandate of Congress.

We begin our discussion with Professor Kenneth Culp Davis' oft-quoted statement:

The procedure of administrative rule making is one of the greatest inventions of modern government.⁹

In view of the important political interests served by public participation in rulemaking, it would be arguable that even in the absence of a specific direction, this unusual situation where Congress effected a profound alteration in an agency's powers while rulemaking was in progress¹⁰ would have called for a new issuance of proposed rules and public participation in rulemaking, as the Commissioner had accorded on his own motion after he had re-

⁸ By order published July 8, 1977 the effective date of the regulation was postponed from January 1, 1978 to July 1, 1979, 42 F.R. 35152.

⁹ *Administrative Law Treatise* § 6.15 at 283 (1970 supp.).

¹⁰ Description of the changes required 8 pages in the House Conference Report, H.R. Rep. No. 94-1005, 94th Cong., 2d Sess. (1976).

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drafted the 1973 regulations in light of our remand. We need not address that question, however, since Congress did give explicit directions in § 501(b) quoted above.

It is true that, if read literally, § 501(b) applies only to regulations amending "any regulation promulgated" under the Act which is inconsistent with the new § 411 and the standard of identity regulations for vitamin and mineral food were not regulations amending a regulation that had been promulgated but rather regulations that were awaiting promulgation, since the previous opinion of this court stayed the regulations and remanded them to the FDA. However, the Commissioner properly did not attempt to read § 501(b) so literally;¹¹ clearly what Congress had in mind in enacting § 501(b) was the Commissioner's much debated proposed vitamin and mineral regulations, which Congress was aiming to restrict. Rather the Commissioner sought to justify his decision not to engage in public rulemaking on the basis, sound enough as an abstract proposition, that when Congress referred to 5 U.S.C. § 553 (b), it included the exceptions therein contained. In effect the Commissioner reads § 501(b) as meaning only that if he decided that further procedures were needed, these could be of the notice and comment type prescribed by 5 U.S.C. § 553(b) and (c) rather than the trial type procedure prescribed by § 701(e) of the Food, Drug and Cosmetic Act in cases where it applies.

One answer that might be made to the Commissioner's reliance on the exceptions in 5 U.S.C. § 553(b)(B) is that the Commissioner did not include in the October 19, 1976 rules the statement required in the parenthetical clause and that it was too late for him to do so on a petition for reconsid-

¹¹ In any event the proposed labelling regulations constituted an amendment of a 1955 regulation, 21 C.F.R. part 25. See 504 F.2d at 767.

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eration.¹² While such a denial of a *locus poenitentiae* might seem unduly literalistic, cf. *Nader v. Sawhill*, 514 F.2d 1064, 1068 (TECA 1975), we are not sure that is necessarily so. Congress could well have wished to require an agency to address its mind to whether a case fell within the exceptions before it committed itself to final regulations, not after it had done so without complying with 5 U.S.C. § 553(b) and (c) procedures and thereby created a need for self-justification.¹³ At the very least, justifications after the event are somewhat suspect. See *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156,

12 The Commissioner argues that he presented an adequate statement of reasons when he announced in the October 19, 1976 Federal Register:

Furthermore, recognizing the will of Congress, the Commissioner has moved expeditiously also to amend the regulations so that they no longer purport to limit the inclusion of ingredients or maximum potency of vitamins or minerals subject to the new legislation.

41 F.R. 46170. By no stretch of the imagination could this statement be said to articulate reasons to forego the notice and comment procedures of 5 U.S.C. § 553. Rather, it merely describes what the Commissioner had done.

13 Although not faced with the precise problem here under discussion, a number of courts have insisted that agencies preface regulations issued under the good cause exception of § 553(b)(B) with the requisite "finding and a brief statement of reasons therefor," striking down regulations where agencies had made considerably more serious attempts at a statement of reasons than the Commissioner initially made here. See *Kelly v. United States Dep't of Interior*, 339 F. Supp. 1095, 1101 (E.D. Cal. 1972); *Akron, Canton & Youngstown R.R. v. United States*, 370 F. Supp. 1231, 1241 (D. Md. 1974); *City of New York v. Diamond*, 379 F. Supp. 503, 515-17 (S.D.N.Y. 1974). *Nader v. Sawhill*, *supra*, 514 F.2d at 1068, is not a significant departure from this line of cases. Good cause was provided there by the Cost of Living Council's concern that announcing an increase in the price of oil 30 days before its effectiveness would cause producers to withhold oil from the market until they could take advantage of the increase, a "calamitous" circumstance in light of the then-pending Arab oil embargo. Indeed, the same court later cited *Nader v. Sawhill* as one of a line of cases in which it took "judicial notice of the emergency nature of the legislation and accompanying regulations" in order to meet the requirements of 5 U.S.C. § 553. *Tasty Baking Co. v. Cost of Living Council*, 529 F.2d 1005, 1014-15 (TECA 1975).

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168 (1962); *National Nutritional Foods Ass'n, supra*, 504 F.2d at 789. However, we need not pass on this since the Commissioner would not have been warranted in dispensing with public rulemaking even if he had included in the October 19, 1976 regulations the findings of impracticability and lack of necessity which he made on April 19, 1977.

The legislative history of the Administrative Procedure Act demonstrates that Congress intended the exceptions in § 503(b)(B) to be narrow ones. The Senate Report, No. 752, 79th Cong. 1st Sess. (1945), reprinted in the Legislative History of the Act at 200, stated:

The exemption of situations of emergency or necessity is not an "escape clause" in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. "Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings. "Unnecessary" means unnecessary so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved. "Public interest" supplements the terms "impracticable" or "unnecessary"; it requires that public rule-making procedures shall not prevent an agency from operating and that, on the other hand, lack of public interest in rule making warrants an agency to dispense with public procedure.¹⁴

See also *American Iron and Steel Institute v. EPA*, slip op. at 11 (3 Cir. Sept. 14, 1977) (citing legislative history

¹⁴ The House Report, H.R. Rep. No. 1980, 79th Cong., 2d Sess. (1946). Legislative History at 258, uses identical language.

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to support proposition that 5 U.S.C. § 553(b)(B) exceptions are to be narrowly construed).

The final regulations do not meet this strict standard. The exception for impracticability is plainly unavailable. "The due and required execution of the functions" of the FDA would hardly have been "unavoidably prevented" by further public rulemaking in the fall of 1976 with respect to regulations which already were 14 years in the making and which the agency now has stayed on its own motion until July 1, 1979. Likewise, the Commissioner cannot resort to the exception invoking the "public interest" since requiring public rulemaking proceedings would not have prevented the FDA from operating or otherwise have harmed the public weal. In fact the Commissioner relies much more heavily on the claim that public participation was unnecessary; he argues that since Congress had spoken, there was nothing more for the public to say and the agency's duty was simply to excise portions of the proposed regulations that Congress had placed beyond its power. But the agency's task went beyond a mere wielding of scissors. While the 1976 legislation withdrew old powers, it also imposed new duties, notably with respect to labeling, see § 411(b)(2). Indeed in the preamble to the October 19, 1976 regulations, the Commissioner had noted that the new legislation "requires extensive labelling revisions even in the absence of the new FDA regulations." 41 F.R. 46170. In view of the history of the administrative proceedings and the legislative struggle, there was no basis for the Commissioner's believing that the public would not be "particularly interested" in his next move; if he ever entertained such a belief, the "urgent petition" of November 30, 1976 must have debunked him of it. Cf. *Texaco, Inc. v. FPC*, 412 F.2d 740, 743 (3 Cir. 1969). Moreover, the problem created by the 1976 amendment went deeper than

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the Commissioner would have it. His promulgation of a standard of identity for vitamin and mineral preparations had rested primarily, not on considerations of safety, but on the need to lessen confusion among consumers. As had been said in the Commissioner's finding 22, which we cited in our opinion, 504 F.2d at 776:

The establishment of qualitative and quantitative limits on the composition of dietary supplements will reduce consumer confusion concerning choice of dietary supplements by ensuring a basically rational formula for all products.

By the 1976 legislation Congress pronounced that it was not concerned about this for the public in general or, at least, that it considered the costs incident to reducing consumer confusion for the entire public by the FDA's proposed standard of identity to be too high in relation to the benefits to be achieved. Cf. 504 F.2d at 782-83. While Congress permitted the agency to impose a standard of identity in the three instances cited in § 411(a)(2), it did not require this. Presumably it wished the agency to consider whether to impose a standard and, if so, what standard for the three permitted cases.¹⁵ The record which

¹⁵ Senator Proxmire, one of the sponsors of the 1976 legislation, said during debate on the bill that the exemption of children and pregnant or lactating women from the restrictions of the statute

does not mean that the FDA can merely, once again, arbitrarily set limits on vitamin RDA's for pregnant or lactating women or children and proclaim that an otherwise safe vitamin or mineral is a drug because it is 150 percent of the RDA or meets some other arbitrary standard. It is our view that under the recent appellate court decision the FDA would have to have some objective standard on which to base its limitations of vitamins or minerals for use by these groups.

121 Cong. Rec. S21856 (daily ed. Dec. 11, 1975). While it is unclear what "objective standard" Senator Proxmire had in mind, it is plain that he expected thorough reexamination of existing proposals, and not a mere mechanical excision.

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we found to have furnished substantial evidence to support the standard of identity previously prescribed thus might not serve the same office with respect to one of the limited applications now permitted.¹⁶ At least those who did not believe so were entitled to an opportunity to present their views, with the agency and other opposing interests, if unpersuaded, then having an opportunity to show why these were wrong. In short the FDA's task was not simply to grant an exemption from provisions in the proposed regulations which the 1976 legislation had rendered illegal but to promulgate regulations which it deemed suitable in the light of what Congress had done. Performance of so major a task did not come within the limited exceptions of 5 U.S.C. § 553(b)(E).

On the other hand the Commissioner properly rejected the petitioners' claim that further trial type procedures under § 701(e) were required. The 1976 statute specifically directed that further procedures should be of the sort prescribed by § 553 and not by § 556 of Title V. Congress, which must have been fully aware of the snail-like pace and the Gargantuan record which compliance with § 701(e) had entailed, had had enough, so far as these regulations were concerned. In bringing these proceedings to an end, the FDA was relieved of the need of engaging in the trial type procedures that had been required when they began. We add that we do not think the agency is required to consider objections which could have been but were not previously raised, which were raised and overruled but

¹⁶ In saying this we are aware that the 1973 regulations had permitted different potencies for children under 4 years of age and for pregnant or lactating women than for adults and children 4 or more years of age, see 504 F.2d at 769. As we understand it, the effect of the exemption, now § 105.85(e), is that the potency columns headed "Adults and children 4 or more years of age" have no application to adults but apply only to children more than four and less than twelve, if the other conditions of exemption are met.

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were not appealed to this court, or which this court decided favorably to the agency, unless the objection takes on a significantly new aspect in light of the 1976 amendments.

Although we could end our opinion at this point, except for treating some of Dr. Robinson's claims, and we shall not deal with many of petitioners' objections (Brief, points IV-VII) that may disappear or be better answered by the Commissioner as a result of new rulemaking, our desire to assist in bringing these proceedings to a conclusion impels us to discuss a few additional points.

(2) *Petition of Dr. Robinson.*

We have carefully reviewed Dr. Robinson's many procedural and substantive objections to the cross-examination of Dr. Harper and to the Commissioner's conclusion that the U.S. RDA's had been properly prepared and furnished a sufficient basis for the potency limits in the standard of identity. We have concluded that these would be without merit, largely for the reasons stated in the Commissioner's careful analysis in October, 1976, 41 F.R. 46157-65, if the issue had remained the same as it was at the time of our remand and of Dr. Harper's cross-examination. The agency thus is not required to replough ground which has been so thoroughly tilled.¹⁷ However, as indicated in the previous section of this opinion, the issue under the 1976 legislation is the possibly different one of the propriety of using the U.S. RDA's as a basis for a standard of identity for the three classes of consumers there specified. The rulemaking should therefore permit notice and comment on the issue whether, assuming that the U.S. RDA's were proper for the broad purpose for which

¹⁷ Specifically, we reject the attack on Doctor Harper as biased, the objections to the evidentiary rulings of the ALJ, and the general methodological challenges to the RDA's. The only further inquiry that we sanction here is the one delineated in text.

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they were used in the 1973 regulations, they are suitable for the special purposes now permitted.

(3) *Retention of minimum potency requirements.*

Petitioners contend that the Commissioner erred in retaining the minimum potency requirements for dietary supplements. Both the Commissioner and the petitioners cite the statement in the conference report on the 1976 legislation that

[N]ew section 411(a)(1)(A) of the Act prohibits the Secretary from using his existing authority under sections 201(n) or 403 of the Act (relating to misbranding) or under section 401 of the Act (relating to standards of identity) to impose maximum limits on the potency of safe vitamins and minerals contained in products subject to the conference substitute. This provision would not restrict the Secretary from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts.

H.R. Rep. No. 94-1005, *supra* at 26.

From this, the Commissioner argues that the new statute did not limit his authority to prescribe minimum potencies. Petitioners grant that the Commissioner has this authority, but contend that, in accordance with the mandate of the conference report, he exercised it on the basis that the minimum potencies were necessary to prevent addition of insignificant or useless amounts of vitamins or minerals from being included in dietary supplements, 41 F.R. 46166, and that this differs from his original rationale, which was to prevent consumer confusion. To proceed under the new rationale, petitioners argue, the Commissioner must develop new evidentiary support.

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We do not think the Commissioner promulgated the minimum potency requirements with the sole aim of avoidance of consumer confusion. He included in his original findings of fact statements such as:

12. Some dietary supplements contain so little of a named nutrient as to be insignificant in human nutrition. . . . There is a sound scientific basis for establishing quantitative minimums on the nutrient ingredients for dietary supplements since only substantial amounts of nutrients should be represented for purposes of dietary supplementation. . . .

13. Certain dietary supplements are objectionable because they must be taken in large numbers of units for the user to get the designated amounts of the nutrients involved. . . . In establishing a standard of identity for dietary supplements it is medically and pharmacologically sound to establish a standard of identity for dietary supplements on the basis of units suitable for and practical of consumption in one day.

38 F.R. 20734-35. See also 38 F.R. 2158 ("Establishing 50 percent as the lower permissible limit provides protection for the consumer from inadequate amounts of nutrients for supplementation purposes."). The fact that the new legislation may prevent the Commissioner from excluding from dietary supplements compounds he thinks worthless in no way undermined his authority, which Congress specifically preserved, to prescribe minimum potencies for vitamins and minerals. Nor do we think it inconsistent that the Commissioner has set one standard of significance for representations concerning nutrients in food which constitutes a portion of a meal, 21 C.F.R. 101.9(c)(7)(v), and another for determining permissible levels of nutrients in a dietary supplement. The very purpose of a dietary sup-

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plement is to provide a significant amount of such nutrients. We hold to our previous opinion that the limits the Commissioner has set are "clearly within the language and purpose of § 401." 504 F.2d at 774 n.10.

(4) *Compliance with this court's remand.*

Petitioners complain that the Commissioner failed to comply with our directions on remand in five respects:

(a) *Inclusion of essential vitamins and minerals for which no U.S. RDA's have been established.*

Petitioners allege that the FDA has failed to comply with our direction, 504 F.2d at 786-87, to permit the inclusion of the vitamins and minerals recognized to be essential to human nutrition but for which no U.S. RDA's have been established. See notes 2 and 3, *supra*. The Commissioner answers that the final regulations do permit these elements to be included in "nonconforming" multivitamin dietary supplements¹⁸ or in single ingredient vitamin or mineral preparations. With respect to the continued exclusion of these vitamins and minerals from multivitamin and/or multimineral preparations to which the original standard of identity applies, the Commissioner relies on a passage in his statement initiating the 1975 rulemaking, 40 F.R. 23246, that "there currently is no body of scientific evidence establishing that American diets are deficient in any" of these vitamins and minerals and thus "it would be wasteful and misleading to include them in standardized multicomponent dietary supplements consumed by individuals who wish to assure themselves that they consume the

¹⁸ We understand this to mean the products for which the Commissioner's authority to prescribe maximum potencies or permissible combinations of vitamins or minerals above the minimum potencies was withdrawn by the 1976 legislation; if so, the grant of this permission scarcely represents a response by the Commissioner to our direction.

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range of vitamins and/or minerals important for good nutrition." This is nothing more than we previously had before us and is hard to reconcile with the inarticulate premise that inclusion would have been permitted if U.S. RDA's had been established and with the permission to include these nutrients in preparations consisting of a single vitamin or single mineral for which U.S. RDA's have been prescribed. If there is evidence to support the Commissioner's conclusion, in the new world of the 1976 legislation, additional to what we previously found insufficient when the Commissioner had a broader power to prescribe a standard of identity, the Commissioner may adduce it in the further rulemaking; we have no desire to insist on the letter of our prior opinion if the Commissioner can produce evidence to justify his action.

(b) Variances from the regulations.

Petitioners criticize the Commissioner's compliance with our directions, 504 F.2d at 785, "that § 80.1(b)(4) be modified to permit upward revisions in the maxima for particular vitamins or minerals" in the light of scientific research and "that the criteria be broadened to conform to the standards of § 401." Petitioners requested the FDA to say that in ruling on applications for upward variances and added combinations, it would be guided by the factors mentioned by us, 504 F.2d at 785-86. The agency declined the latter request, as it properly could, and responded to our direction by saying only that it would allow variances only if a petitioner produced "data to show that such amendment will promote honesty and fair dealing in the interest of consumers," 41 F.R. 46171. See 21 C.F.R. 105.85(a)(5). The Commissioner says that this met our direction since it echoes the preamble to § 401 with respect to his authority to promulgate a standard of identity. This

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is a bit too facile. Our holding was that in light of the state of scientific information, the Commissioner had exceeded his mandate if he did not allow for modification of the regulations as knowledge advanced. The proponent of a change discharges his burden if he can show that it will achieve the Commissioner's goals to the same extent as the existing regulations; he should not be required to show it will constitute an improvement.

(c) *Proviso with respect to iron.*

In our prior opinion, 504 F.2d at 801-02, we approved the prohibition of label statements suggesting "[t]hat a balanced diet of ordinary foods cannot supply adequate amounts of nutrients," 504 F.2d at 799 n.68, with one important exception. We referred to "strong and uncontradicted evidence that it was very difficult for women of child-bearing age and for children to obtain an adequate supply of [iron] even from a balanced diet." We directed that, unless the Commissioner could contradict this, he should insert "a proper qualification." The qualification made was, 21 C.F.R. 105.60(b)(2):

[R]epresentations may be made that it is often impractical to supply the iron requirements of infants, children, and women of childbearing age with a diet of conventional foods.

We agree with petitioners that this does not entirely capture our direction. It could well be read as saying that where it was "practical" for infants, children and women of childbearing age to obtain "a diet of conventional foods," their needs for iron would be fully met. The Commissioner gave no explanation for not complying with our mandate; counsel now tell us that he followed the language of finding of fact number 45 in the 1973 report, 38 F.R. 20715. How-

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ever, the evidence went beyond the finding, as we intimated. Unless adequate contradictory evidence should now be forthcoming, the Commissioner shall comply with our direction with respect to iron.

(d) Refusal to make qualifications in respect of Vitamin B₆, Folic Acid and Magnesium.

In our previous opinion, 504 F.2d at 801-02 n.73, we noted that while some petitioners claimed that a balanced diet did not supply adequate amounts of vitamin B₆, folacin and magnesium, they had failed to supply us with the portions of the record alleged to demonstrate this. Although we had not so required, the Commissioner gave further consideration to this and concluded that he was "not aware of any substantial evidence to indicate that a balanced diet of ordinary foods cannot supply adequate amounts of these three nutrients." 41 F.R. 46169. We have reviewed the extracts of testimony now filed by petitioners and see no basis for faulting the Commissioner. Indeed, some of the testimony undermines petitioners' claims that vitamin B₆ and folacin are inadequately supplied by a normal diet. See WD-46, Olson, at 10.

(e) Difference between natural and synthetic vitamins.

We previously upheld, 504 F.2d at 805, a provision of the regulations, now § 105.60(b)(6), proscribing representations "that a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added." Petitioners complain that the Commissioner himself has now recognized such a difference with respect to vitamin K, 40 F.R. 23248. We do not think this exception with respect to a vitamin which is neither on the mandatory nor on the optional list requires a qualification. If sellers

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of vitamin K in its natural form desire relief, we assume the Commissioner will grant any relief that is warranted, see 504 F.2d at 784.

(5) *Vitamins and minerals as food additives.*

A more important controversy relates to what is now § 105.85(f). This provision, which appeared for the first time in the May 1975 proposed rules, 40 F.R. 23249, now begins:

Restrictions of the maximum potency of a vitamin or mineral may be imposed for reasons of safety by the act or by regulation.

It then cross-references seven code provisions defining certain dosages of specific vitamins or minerals as dangerous.¹⁹ Petitioners focus on the paragraph that follows:

(8) Any vitamin or mineral which is included in a dietary supplement and which is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of

¹⁹ The extent to which petitioners challenge these seven cross-references is unclear. Preliminarily we note our assumption that the Commissioner will drop the cross-references to §§ 250.109 and 250.110 since those sections have recently been declared invalid by this court. *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (1977). The other regulations—effectively designating certain nutrients as food additives at specified potencies—to which the Commissioner cross-referenced have been in effect at least since 1974, see 21 C.F.R. §§ 3.15, 121.10, 121.101 (d)(5), 121.1073, 121.1134 (1974), and would, we think, be applicable to dietary supplements even without the cross-references. This is the import of our holding, *infra*, concerning the broad definition of “food additive.” See also 21 C.F.R. § 105.85(a)(4). Thus, if petitioners mean to challenge the inclusion of these cross-references, they are foreclosed from doing so because they have suffered no injury. If, on the other hand, they mean to challenge the underlying regulations, this is neither the proper time nor the proper forum.

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its intended use is a food additive within the meaning of section 201(s) of the act; and pursuant to sections 402(a)(2)(C) and 409 of the act, such inclusion is illegal in the absence of a food additive regulation approving such inclusion. A listing of some of the vitamins, minerals, and compounds with vitamin and/or mineral properties which are generally recognized as safe, and which thus may lawfully be included in a dietary supplement without a food additive regulation, appears at Subpart F of Part 182 of this chapter.²⁰

Petitioners say that having been foiled by us, 504 F.2d at 788-89, and by Congress, see § 411(a)(1)(B), in his effort to classify high potency vitamins and minerals as drugs, the Commissioner is now seeking to reach essentially the same goal by threatening to treat added quantities as food additives.²¹

Examination of petitioners' objection requires a threading through the labyrinthine provisions of the Food, Drug

²⁰ In the proposed rules published in May 1975, 40 F.R. 23248, the Commissioner advised "that he is planning to initiate new rule making to particularize more comprehensively than existing § 121.101(d)(5) the vitamins, minerals and compounds with vitamin and/or mineral properties which are GRAS (specifying potency limitations where recognition of safety depends upon such limited use) and to list as well those substances which are not GRAS at any level of use. Proposals for such rule making will appear in the FEDERAL REGISTER." He also announced his tentative views as to which vitamins and minerals (and in what potencies) were or were not generally recognized as safe or, in the FDA acronym, GRAS.

²¹ In addition to the statutory objection hereafter discussed, petitioners complain that addition of this provision was not within the scope of the remand. However, our order did not prohibit the Commissioner from making further changes in the regulations so long as they were not inconsistent with our opinion and petitioners were offered notice and an opportunity to comment on this additional provision, which they exercised. We note that since this was a regulation under § 409, rather than under §§ 401 or 403(j), the hearing on the record requirements of § 701(e) are not applicable.

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and Cosmetic Act. Section 201(s) provides, with exceptions unnecessary to specify here:

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use

Food is defined in § 201(f):

The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Under § 402(a)(2)(C) a food is deemed to be adulterated:

if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409. . . .

Section 409 rounds out the picture by providing in pertinent part:

(a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed

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to be unsafe for the purposes of the application of clause (2) (C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

Section 301 prohibits, *inter alia*, introduction of adulterated foods into interstate commerce, receipt of adulterated goods or adulteration of goods in interstate commerce. Section 302 authorizes injunctive actions for violation of § 301; § 303 prescribes criminal penalties for such violations; and § 304 provides for seizure of adulterated foods.

Petitioners contend that vitamins and minerals are foods within § 201(f), see also the new § 411(c)(1) added in 1976, and that in the nature of things a "food" cannot be a "food additive," especially when it is just more of the same. Recognizing that the Commissioner must have power to prevent the sale of vitamin and mineral preparations of such high potency as to be dangerous, they say the Commissioner must proceed under more general provisions relating to adulteration on a case by case basis see, e.g. § 402(a)(1), (3)-(7), (b), rather than the more readily enforceable provisions relating to food additives.

The contention has its force, but, as the Fifth Circuit has noted

The sole criterion for identifying a food additive is whether a substance which may become a component of or affect the characteristics of any food be not generally recognized among qualified experts as having been shown to be safe. . . .

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United States v. 41 Cases, More or Less, 420 F.2d 1126, 1131 (1970). We do not believe a substance gains immunity from this criterion merely because it also qualifies as a food, cf. *United States v. Article of Food Consisting of 10 Drums, More or Less, of Orotic Acid*, 414 F.Supp. 793 (E.D. Mo. 1976). Further, as Judge Gurfein has recently written for us:

Yet, when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as "consistent with the Act's overriding purpose to protect the public health". *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). As Justice Frankfurter said in *United States v. Dotterweich*, 320 U.S. 277, 280 (1943):

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

Thus, a provision concerning "food additives" has been held to include even poisonous substances which have not been "added" by human hands. *United States v. Ewig Bros. Co.*, 502 F.2d 715, 721-24 (7th Cir. 1974) (Stevens, J.), cert. denied, 420 U.S. 945 (1975).

United States v. Nova Scotia Food Products Corp., slip opinion 6433, 6441-42, decided December 15, 1977 (footnote omitted). As then Judge Stevens wrote in the case cited, 502 F.2d at 721 (footnote omitted):

The legislative history of the 1958 Bill indicates concern about the difficulties present when dangerous substances could not be proscribed by per se rules.

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Since Congress used broad language in order to eliminate such difficulties, we should not construe it narrowly.

Congress has vested the Commissioner with broad "authority to promulgate regulations for the efficient enforcement" of the Food, Drug and Cosmetic Act, § 701(a), see *National Nutritional Foods, Inc. v. Weinberger*, 512 F.2d 688, 695-98 (2 Cir.), *cert. denied*, 423 U.S. 827 (1975); H.R. Rep. No. 94-1005, *supra* at 27-28, and we see no reason why he cannot determine that too much of even a good thing may come within the definition of a "food additive."

Still, more important, Congress, which most likely was aware of the May 1975 regulations, seems to have held that view. The Senate decided not to include in the 1976 legislation—a provision prohibiting FDA from regulating safe vitamins, minerals, and associated ingredients as food additives, stating in the report on the bill:

This was not done for two reasons. First of all, it is unnecessary. It would be inappropriate and contrary to the intention of this Title for the FDA to treat vitamins, minerals, and their associated ingredients about whose safety there currently is no doubt, as food additives. There are those who considered vitamins and minerals essentially foods with a long history of safe use. The authors rejected that course of action on grounds that there was insufficient evidence to support such a course of action at this time.

Second, there are some nutrients and ingredients or natural chemicals which are tangentially a part of vitamins or minerals which currently may be considered food additives because of their potential toxicity. We did not wish to prevent the FDA from acting in these circumstances. For the agency to do so based

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on the policies on potency and combinations which this amendment endorses, however, would be inappropriate.

S. Rep. No. 94-509, 94th Cong., 1st Sess. 40-41 (1975). And the House Conference Report observed:

Similarly, if any vitamin, mineral or other food ingredient is not generally recognized as safe by qualified experts and meets the other criteria of the definition of a "food additive" under section 201 (s) of the Act, it would be subject to regulation under section 409 of the Act. If such a vitamin, mineral or other ingredient is intentionally added to a food, such food is adulterated (within the meaning of section 402 (a)(2) (C) of the Act) unless its use is in conformity with a regulation issued by the Secretary which prescribes the conditions under which it may be safely used or exempts it for investigational use by qualified experts. It is on precisely this basis that the Secretary has, by regulation, restricted the potency of the vitamin folic acid that may be added to a food.

H.R. Rep. No. 94-1005, *supra* at 28.

We therefore find no infirmity in § 105.85(f).²²

(6) *Potency on expiration date.*

The final regulations contain a provision also present in the 1973 regulations, requiring that the labels of dietary supplements carry an expiration date and that on such date the dietary supplement "contain not less than the quantity of each such vitamin and/or mineral, as set forth on its label," 21 C.F.R. § 105.85(l). Petitioners object to the latter provision because of its failure to allow for any

²² We assume, of course, that the Commissioner will act consistently with the second parenthetical clause of § 201(s).

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tolerance, as is done in the U.S. Pharmacopoeia. Since this point could have been but was not taken by petitioners on the prior review, we think it now comes too late, although the Commissioner is free to consider it if he desires.

The regulations are vacated and the cause is remanded to the Commissioner for further proceedings consistent with this opinion.

RULES AND REGULATIONS

§ 569.4—Maximum rate of return payable on certificate accounts.

(d) *Amount limitation.* An insured institution may not advertise or pay a rate of return, higher than the maximum rate prescribed for regular accounts, on certificate accounts issued at a time when the total of certificate accounts receiving a rate of return (including any deferred return or bonus applicable to a period of less than 3 years) higher than the maximum rate prescribed for regular accounts exceeds 50 percent of total withdrawable accounts.

(Sec. 4, 80 Stat. 823; 12 U.S.C. 1425b)

Resolved further that, as the foregoing amendment is designed to adjust the operations of savings and loan associations insured by the Federal Savings and Loan Insurance Corporation as of the beginning of the next dividend distribution period to changed economic conditions emerging during the current dividend period, the Board hereby finds that deferral of the effective date of the said amendment pursuant to the provisions of § 508.14 of the General Regulations of the Federal Home Loan Bank Board (12 CFR 508.14) and 5 U.S.C. 553(d) is not consistent with the public interest and provides that the said amendment shall be effective as hereinbefore set forth.

By the Federal Home Loan Bank Board.

[SEAL] GRENVILLE L. MILLARD, Jr.,
Assistant Secretary.

[F.R. Doc. 66-13420; Filed, Dec. 13, 1966;
8:49 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Agency (Docket No. 7790; Amdt. 151-14)

PART 151—FEDERAL AID TO AIRPORTS

U.S. Share of Project Costs in Public Land States

The purpose of this amendment is to revise the table in § 151.43(c) of Part 151 of the Federal Aviation Regulations. The table sets forth, in percentage, the U.S. share of the costs of an approved project for airport development in each state where the unappropriated and unreserved public lands and nontaxable Indian lands (individual and tribal) exceed 5 percent of the total area of all lands therein. Section 151.43(c) reflects the requirement of section 10(b) of the Federal Airport Act (49 U.S.C. 1109).

The U.S. percentage share of project costs in each of these states has been redetermined on the basis of recent information furnished by the Department of the Interior. This redetermination has resulted in changes of the percentages for all states listed in the table except Alaska, Arizona, Colorado, and Nevada.

The procedural and effective date requirements of section 553 of Title 5, U.S. Code, do not apply to this amendment because it is within the exception in that section relating to public grants, benefits, and contracts, and this amendment may be made effective upon publication in the Federal Register.

In consideration of the foregoing, the table in § 151.43(c) of Part 151 is amended, effective December 14, 1966, to read as follows:

§ 151.43 U.S. share of project costs

(c)

State	Percent
Alaska	62.50
Arizona	61.00
California	53.63
Colorado	53.30
Idaho	55.85
Montana	53.03
Nevada	62.50
New Mexico	56.31
Oregon	55.64
South Dakota	52.55
Utah	60.94
Washington	51.53
Wyoming	57.32

(Secs. 1-15, 17-21, Federal Airport Act; 49 U.S.C. 1101-1114, 1116-1120)

Issued in Washington, D.C., on December 7, 1966.

WILLIAM F. MCKEE,
Administrator.

[F.R. Doc. 66-13350; Filed, Dec. 13, 1966;
8:45 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 1—REGULATIONS FOR ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

PART 5—FOOD; EXEMPTIONS FROM LABELING REQUIREMENTS

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 80—DIETARY SUPPLEMENTS AND VITAMIN AND MINERAL-FORTIFIED FOODS

PART 125—FOOD FOR SPECIAL DIETARY USES

Order Staying Effective Date of Regulations; Amending Regulations; and Allowing Additional Time for Filing Objections

In the matter of revising the regulations for food for special dietary uses:

On June 18, 1966, orders were published in the Federal Register (31 F.R. 8521 et seq.), to become effective December 15, 1966, exempting from labeling requirements certain artificially sweetened foods (21 CFR 5.5), establishing definitions and standards of identity for dietary

supplements of vitamins and minerals and for vitamin and mineral-fortified foods (21 CFR Part 80), and revising the regulations for food for special dietary uses (21 CFR Part 125). The order also deleted § 1.11. Within the 30-day period permitted by the order, objections were filed, together with requests for a public hearing. Therefore, pursuant to section 701(e), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)) and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.120; 31 F.R. 3008): It is ordered, That the effective date of § 5.5, Part 80, and Part 125, published June 18, 1966, be stayed and also that the effective date of the deletion of § 1.11 be stayed.

At a later date the Commissioner will announce by publication in the Federal Register the date and place for the commencement of the public hearing to be held upon the following issues raised by the objection:

I. Issues concerning § 5.5. Whether the conditions of exemption set forth in § 5.5 Certain foods with added artificial sweetener not intended for special dietary use are reasonable and necessary to fully inform purchasers of the value of such foods.

II. Issues concerning Part 80, A. With respect to § 80.1 Dietary supplements of vitamins and minerals; identity; label statements:

1. Whether it will promote honesty and fair dealing in the interest of consumers, and will assist in carrying out the purpose of the law of providing full information to consumers as to the value of such foods for special dietary use, to promulgate a standard of identity for dietary supplements of vitamins and minerals.

2. Whether such standard should limit the nutrients contained therein to those listed in § 80.1(b), as amended by this order.

3. Whether such standard should limit the minimum and maximum amounts of nutrients supplied to those listed in § 80.1(b), as amended by this order.

4. Whether the label of the dietary supplement should bear the statement, as prescribed by § 80.1(e), "Multivitamin supplement," "Mineral supplement," "Multivitamin and mineral supplement," "Vitamin supplement," "mineral supplement," or "Vitamin and mineral supplement," as the case may be, the blanks to be filled in with the name(s) of the vitamins and/or minerals which the supplement is represented to contain.

5. Whether the label of dietary supplements should bear the statement prescribed by § 80.1(f), as amended by this order, which reads:

Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

as a necessary means of fully informing consumers of the value of such dietary supplements for special dietary use.

5. Whether the label of the dietary supplement should bear the name and amount of each vitamin and mineral supplied by the supplement, as prescribed by § 80.1(g).

7. Whether the label of the dietary supplement should name the ingredients used to provide the vitamins and minerals, and the source of these ingredients.

8. Whether the label of the dietary supplement containing one or more vitamins should bear, as prescribed by § 80.1(k), as amended by this order, an expiration date which will assure that the supplement contains the full declared level of the vitamins when purchased by the consumer.

B. With respect to § 80.2 Vitamin and mineral-fortified foods; identity; label statements:

1. Whether it will promote honesty and fair dealing in the interest of consumers, and will assist in carrying out the purpose of the law of providing full information to consumers as to the value of such foods for special dietary use, to promulgate a standard of identity for vitamin and mineral-fortified foods.

2. Whether it will promote honesty and fair dealing in the interest of consumers to permit fortification of foods only in those classes of foods listed in § 80.2(c), as amended by this order, and to exclude from the standard those classes of foods listed in § 80.2(b), as amended by this order.

3. Whether it will promote honesty and fair dealing in the interest of consumers to limit the fortification of foods to the nutrients listed, in the amounts stated, and under the conditions set forth in § 80.2(c), as amended.

4. Whether any of the classes of foods listed in § 80.2(c), as amended, should be eliminated from the standard.

5. Whether the designated serving set forth in § 80.2(c), as amended, for each class of food is reasonable.

III. Issues concerning Part 125. A. With respect to § 125.1 Definitions and interpretations of terms:

1. Whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to define "special dietary use" as set forth in § 125.1(a).

2. Whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to establish "recommended dietary allowances" for essential nutrients.

3. Whether the "recommended dietary allowances" as set forth in § 125.1(b), and amended by this order, are reasonable.

4. Whether the definition of "artificial sweetener" in § 125.1(c) is reasonable.

B. With respect to § 125.2 General label statements; dietary properties; value; placement, whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods bear a statement as

required and limited by that section, as amended by this order.

C. With respect to § 125.3 Label statements relating to vitamins and minerals, whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses, to require that the labels of such foods by reason of their vitamin or mineral content bear a statement of the percentages of the recommended dietary allowances of such vitamins and minerals contained in such food, with the limitation that vitamin and mineral supplements and foods fortified with vitamins and/or minerals may not bear on their labels a declaration of any quantity of added vitamins or minerals in the supplements or fortified foods which supply more than 100 percent of the recommended dietary allowance for any nutrient.

D. With respect to § 125.4 Label statements relating to infant food, whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for special dietary uses for infants, to require that the label of such foods bear the statements set forth in that section, as amended by this order.

E. With respect to § 125.5 Label statements relating to food for use in reducing, maintaining, or gaining body weight, whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods represented for use in reducing, maintaining, or gaining body weight, to require that the labels of such foods bear the information required by that section, as amended by this order.

F. With respect to § 125.6 Label statements relating to food for use in the diets of diabetics, whether it is necessary and reasonable, in order fully to inform purchasers of the value of foods for use in the diets of diabetics, that such foods be labeled as such and that their labels bear the information required by that section, and whether the term "dietetic" shall be prohibited, or shall be restricted to the labels of food for the diets of diabetics.

The Commissioner has determined that the final orders establishing Part

80 and revising Part 125, published FEDERAL REGISTER of June 18, should be amended in certain minor respects to clarify the orders and in other respects to meet some of the objections filed. Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403(j), 701(e), 52 Stat. 1046, as amended, 1048, 1055, as amended; 21 U.S.C. 341, 343(j), 371(e)), and under the authority delegated to the Commissioner of Food and Drugs by the Secretary (21 CFR 2.120; 31 F.R. 3008), Parts 80 and 125 are amended to read as follows and, although amended hereby, the effective date of these parts is stayed as announced above:

Sec. 80.1 Dietary supplements of vitamins and minerals; identity; label statements.
80.2 Vitamin and mineral-fortified foods; identity; label statements.

AUTHORITY: The provisions of this Part 80 issued under secs. 401, 403(j), 701, 52 Stat. 1046, as amended, 1048, 1055, as amended; 21 U.S.C. 341, 343(j), 371.

CROSS REFERENCES: For other regulations in the chapter concerning dietary foods see §§ 3.3, 3.42, and 5.5 and Part 125.

§ 80.1 Dietary supplements of vitamins and minerals; identity; label statements.

(a) The dietary supplements for which definitions and standards of identity are prescribed by this section are prepared in tablet, capsule, pill, wafer, or similar uniform units, or in powder, granular, flake, or liquid form, and purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and minerals specified in paragraph (b) of this section.

(b) The dietary supplements contain one or more of the following vitamins and minerals within the limits specified in units reasonably suitable for and practicable of consumption in a period of 1 day, and which provide for 1 day no less than the following minimum amounts nor more than the following maximum amounts:

TABLE 1—VITAMIN SUPPLEMENTS

Vitamins	Unit of measurement	Minimum amounts for any person except an infant ¹	Maximum amounts for—				
			Adult	Pregnant or lactating woman	Child 9 through 17 years of age	Child 1 through 8 years of age	Infant (not more than 12 months of age)
MANDATORY FOR MULTI-VITAMIN SUPPLEMENTS							
Vitamin A.....	U.S.P. units.....	1,250	4,000	4,000	4,000	2,500	1,500
Vitamin D.....	do.....	100	400	400	400	400	400
Ascorbic acid (vitamin C).....	Milligrams.....	18	70	100	80	60	30
Thiamine (vitamin B ₁).....	do.....	0.3	1.2	1.2	1.4	0.8	0.4
Riboflavin (vitamin B ₂).....	do.....	0.6	1.7	1.9	2	1.3	0.7
Niacin or niacinamide.....	do.....	5	19	21	22	14	6
OPTIONAL							
Vitamin E.....	International units.....	5	20	20	20	15	5
Vitamin B ₆	Milligrams.....	0.4	2	2	2	1	0.4
Folic acid.....	do.....	0.03	0.1	0.1	0.1	0.05	0.03
Pantothenic acid.....	do.....	2.5	10	10	10	5	2.5
Vitamin B ₁₂	Micrograms.....	3	6	6	6	2.5	2.5

¹ The minimum amounts of the vitamins and minerals of a dietary supplement for an infant are one-half of the respective amounts specified for an infant.

TABLE 2—MINERAL SUPPLEMENTS

Minerals	Unit of measurement	Minimum amounts for any person except an infant ¹	Maximum amounts for—				
			Adult	Pregnant or lactating woman	Child 9 through 17 years of age	Child 1 through 8 years of age	Infant (not more than 12 months of age)
MANDATORY FOR MINERAL SUPPLEMENTS							
Calcium	Milligrams	200	800	1,300	1,400	800	700
Iron	do.	4	15	20	15	12	8
OPTIONAL							
Phosphorus	Milligrams	200	800	1,300	1,400	800	350
Magnesium	do.	75	300	300	300	200	150
Iodine	do.	0.04	0.15	0.15	0.15	0.04	0.03
Copper	do.	0.8	2	2	2	1	1

¹ The minimum amounts of the vitamins and minerals of a dietary supplement for an infant are one-half of the respective maximum amounts specified for an infant.

(c) The vitamins and minerals of the dietary supplements may be supplied by any suitable synthetic or natural substances which are not food additives as defined by section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(d) Suitable substances may be used as preservatives, stabilizers, flavors, colors, sweeteners, seasonings, carriers, bases, vehicles, or to facilitate preparation of the vitamin and mineral substances, and the dietary supplements are so prepared that such substances do not exceed the minimum quantity required to establish their intended physical or technical effect, and the biological availability of the vitamins and minerals is not impaired by the presence of such substances; however, such substances shall not be food additives as defined by section 201(s) of the act, or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(e) The name of the dietary supplement shall appear conspicuously on the main panel of the label. The name of a dietary supplement which contains all of the mandatory vitamins listed in table 1 of paragraph (b) of this section is "Multivitamin supplement"; the name of a dietary supplement which contains both of the mandatory minerals listed in table 2 of paragraph (b) of this section is "Mineral supplement"; and the name of a dietary supplement which contains all of the mandatory vitamins and minerals listed in tables 1 and 2 of paragraph (b) of this section is "Multivitamin and mineral supplement." A dietary supplement which contains less than all of the mandatory vitamins and minerals listed in paragraph (b) of this section shall be designated as "Vitamin supplement" or "Mineral supplement," or "Vitamin and mineral supplement," as the case may be, the blanks to be filled in with the name(s) of the vitamins and/or minerals which the supplement is represented to contain.

(f) Immediately following the name on the main panel of the label of each

dietary supplement, the following statement shall appear in prominent type:

Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

This statement is not required for foods which purport to be or are represented solely for use as a food for an infant, a child 1 through 8 years of age, or a pregnant or lactating woman. Any statement in the label or labeling inconsistent with this statement shall be misleading and shall cause the product to be deemed misbranded within the meaning of sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act.

(g) Immediately following the statement required by paragraph (f) of this section, the label shall bear a statement listing each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement as prescribed in paragraph (b) of this section, together with a statement of the quantity of the dietary supplement to be taken daily and the frequency of ingestion. No other ingredients shall be identified by name except as specifically prescribed by paragraphs (i) and (j) of this section.

(h) [Reserved]

(i) If a chemical preservative, artificial flavoring, artificial coloring, or artificial sweetener is used, the label shall bear the statement: "_____ added as a preservative." the blank to be filled in with the name of the chemical preservative; "Contains _____," the blank to be filled in with the words "artificial flavoring," "artificial coloring," or "artificial sweetener," whichever applies.

(j) When the dietary supplement is in liquid form and contains alcohol, the label shall state the percent by volume of alcohol present.

(k) The dietary supplement containing one or more vitamins shall bear on its outside wrapper or container, as well as on the label of its immediate container, the statement: "Expiration date: _____," the blank to be filled in by the month and year. The expiration date shall be the date selected by the manufacturer, packer, or distributor of the food on the basis of tests or other

information showing that the food, until that date, under the conditions of handling and storage prescribed by directions appearing on its label, or, in the absence of such prescribed directions, under customary or usual conditions of handling and storage, will contain not less than the quantity of each vitamin as set forth on its label.

(l) In addition to the requirements of this part, the dietary supplements shall bear the label statements required by, and shall conform to, Part 125 of this chapter.

§ 80.2 Vitamin and mineral-fortified foods; identity; label statements.

Definitions and standards of identity are established for vitamin and mineral-fortified foods as follows:

(a) The Food and Drug Administration endorses and adopts the "Statement of General Policy in regard to the Addition of Specific Nutrients to Foods" adopted jointly (May 1961) by the Food and Nutrition Board, National Research Council-National Academy of Sciences, and by the Council on Foods and Nutrition, American Medical Association, which reads in part as follows:

The principle of the addition of specific nutrients to certain foods is endorsed, with defined limitations, for the purpose of maintaining good nutrition in all segments of the population at all economic levels. The requirements which should be met for the addition of a particular nutrient to a given food include acceptable evidence that the supplemented food would be physiologically or economically advantageous for a significant segment of the consumer population, assurance that the food item concerned would be an effective vehicle of distribution for the nutrient to be added, and evidence that such addition would not be prejudicial to the achievement of a diet good in other respects.

The desirability of meeting nutritional needs by the use of an adequate variety of foods as far as practicable is emphasized strongly. To that end, research and education are encouraged to insure the proper choice and preparation of foods and to improve food production, processing, storage, and distribution so as to retain their essential nutrients.

Foods suitable as vehicles for the distribution of additional nutrients are those which have a diminished nutritive content as a result of loss in refining or other processing or those which are widely and regularly consumed. The nutrients added to such foods should be the kinds and quantities associated with the class of foods involved. The addition of other than normally occurring levels of nutrients to these foods may be favored when properly qualified judgment indicates that the addition will be advantageous to public health and when other methods for effecting the desired purpose appear to be less feasible.

Scientific evaluation of the desirability of restoring an essential nutrient or nutrients to the diet is necessary whenever technologic or economic changes lead to a nutritionally significant reduction in the intake of a nutrient or nutrients.

Such reduction might result either from a marked decrease in the consumption of an important food or from a considerable increase in the consumption of foods of diminished nutritive quality. Similar action is desirable, when the circumstances concerned above (first paragraph of this policy statement), whenever advances in nutritional

WD-G - GULLBERG
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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D. C.

IN THE MATTER OF)

REVISING THE REGULATIONS FOR)
FOODS FOR SPECIAL DIETARY USES)

21 CFR PART 80)

21 CFR PART 125)

Docket No. FDC-78

WRITTEN DIRECT TESTIMONY
OF GOVERNMENT WITNESS
MARY E. GULLBERG
1805 VIRGINIA STREET
BERKELEY, CALIFORNIA 94703

A. J. A.
Graduate
Page 1

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thesis

WD-G-GULLBERG
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24A. Books on normal nutrition which are recommended include:

Food, The Yearbook of Agriculture, 1959, Foods Without Fads,

by E. W. McHenry published by Lippincott in 1960; Food for

Longer Living, by R. C. Hutchinson, a paperback published by

Cambridge University Press; Food Becomes You, by Ruth Leverton

published by Doubleday in 1961 as a paperback; Nutrition and

Physical Fitness, by Bogert, Briggs and Calloway, the eighth

edition of which was published by Saunders in 1966. There are

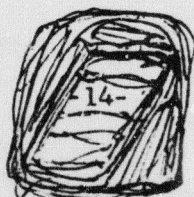
a few others.

25Q. Are dietary supplements of vitamins and/or minerals sold in the Co-op stores?

25A. CCB operates three pharmacies located in three of our shopping centers. These pharmacies as well as our eight food stores stock a line of Co-op label vitamin and mineral supplements, as well as some nationally advertised products for which there is customer demand.

26Q. As a home economist with graduate training in nutrition, have you been satisfied with the composition of the dietary supplements sold in the Co-op stores?

26A. Not entirely. Both our pharmacists and our home economists have been concerned for years that these Co-op formulas were not as well balanced as they should be. Some contain levels of vitamins, such as vitamins A and D, that are excessive in



WD-G. GULLBERG

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our opinion. Some contain only token amounts of some B-complex vitamins, mainly pyridoxine and calcium pantothenate, while others have incorrect ratios of thiamine to riboflavin. Certain formulas do not contain enough calcium to be of much benefit as a supplement for persons who really need to increase their intake of this mineral.

Since these are Co-op label products, and at least theoretically under our control, we have tried very hard to improve them. In fact, I personally have had considerable discussion and correspondence with our suppliers. In a few cases we have been successful, but in most we have not. The reasons for this failure are: 1) a "standard" formula is cheaper because all private label purchasers get the same formula from a given supplier, and 2) buying decisions for Co-op label supplements are made on the basis of a comparison of available private label products with nationally advertised brands, the object being to select those with similar formulations but retailing at lower prices. Our merchandisers are convinced that it is easier to sell Co-op supplements if they can be compared as to ingredients and quantities with advertised products. Therefore our products are often identical to well-advertised formulas.

Because we are able to sell our Co-op label vitamin and mineral supplements for considerably less than the comparable national brand products, our sales of Co-op supplements far

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ADDENDUM PAGE 40

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D. C.

IN THE MATTER OF)

REVISING THE REGULATIONS FOR)
FOODS FOR SPECIAL DIETARY USES)
21 CFR PART 80)
21 CFR PART 125)

Docket No. FDC-78

WRITTEN DIRECT TESTIMONY
OF GOVERNMENT WITNESS
HAROLD E. HARRISON, M.D.
PEDIATRICIAN-IN-CHIEF
DEPARTMENT OF PEDIATRICS
BALTIMORE CITY HOSPITALS
BALTIMORE, MARYLAND

WD-G-HARRISON

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W. J. R.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

REVISING THE REGULATIONS FOR
FOODS FOR SPECIAL DIETARY USES
21 CFR PART 80
21 CFR PART 125

DOCKET NO. FDC-78

(RESIDENCE:
97 ALDERSHOT LANE
MANHASSET, NEW YORK 11030

WD-3A-SEBRELL

1. *Chrysomelidae*
 2. *Curculionidae*
 3. *Chrysomelidae*

[Faint handwritten notes, possibly "W. H. ..."]

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مکتبہ

[Faint handwritten notes, possibly "P.L. ..."]

WD-3A - SEBRELL
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13

there is no need to separate the recommendations for adolescents (age ten through seventeen years) from those of adults.

For the normal individual, there is no good reason for allowing a supplement to contain more than 100% of the Recommended Dietary Allowances, except for the allowance of a reasonable excess in order to provide for possible losses during storage and handling. A reasonable excess is that amount necessary in good manufacturing practice. There is no danger of toxicity. Any normal individual can take considerably more than 100% of the Recommended Dietary Allowance without encountering any risk of toxic effects. Both a minimum and a maximum figure are given. I have set the minimum figure at 25% of the Recommended Dietary Allowance, except for the infant where it is 50%. This is to insure that the product contains enough to make a significant contribution to the intake. A maximum figure is 100% of the Recommended Dietary Allowance.

AMERICAN MEDICAL ASSOCIATION OFFERS IN EVIDENCE
EXHIBIT 3A-6, 0- -3A

25Q. Is there any nutritional reason for vitamin supplements to contain more than the Recommended Dietary Allowance of any vitamin?

25A. No.

26Q. In your opinion, should a vitamin supplement contain a set minimum of each vitamin it purports to contain?

26A. Yes, because the minimum figure should be large enough to make a significant nutritional contribution.

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27Q. What, in your opinion, is enough to make a significant nutritional contribution?

27A. A minimum of 25% of the Recommended Dietary Allowance except for the infant where it is 50%.

28Q. I direct your attention to the table headed Mineral Supplements in subparagraph (b) of Section 80.1 of Hearing Examiner Exhibit 3. In your opinion, is this table a reasonable tabulation of the required levels of nutrients in a mineral supplement?

28A. No.

29Q. What is the basis for your opinion?

29A. The recommendations made in Exhibit P-651 is based upon information which was not available at the time that the table in subparagraph (b) in Section 80.1(b).

30Q. In your opinion, should the table on the last page of Exhibit P-651 be substituted for the table in Section 80.1(b)?

30A. No.

31Q. What is the basis for your opinion?

31A. The table contains considerable detail because it was written for professional people. I believe that it could be modified to make it more easily understood and of more practical usefulness to nonprofessionals.

32Q. Have you prepared a tabulation which in your opinion should be substituted for the table contained in Section 80.1(b)?

WD-3A- SEBRELL
ADDENDUM PAGE 45 16

Recommended Dietary Allowance without encountering any risk of toxic effects. The maximum figure is 100% of the Recommended Dietary Allowances as given in Exhibit P-651. The minimum figure is 25% of the Recommended Dietary Allowances, except for the infant where it is 50%.

AMERICAN MEDICAL ASSOCIATION OFFERS IN EVIDENCE
EXHIBIT 3A-7, 0- -3A

35Q. I note that there are a total of 11 vitamins and 6 minerals contained in the two tables in exhibits 3A-6 and 3A-7. In your opinion, are there any other nutrients which should be permitted in vitamin and mineral supplements? VAE

35A. No.

36Q. In your opinion is there any nutritional reason for mineral supplements to contain more than the Recommended Dietary Allowance of any mineral?

36A. No.

37Q. In your opinion is there any nutritional reason for mineral supplements to contain more than the Recommended Dietary Allowance of any mineral?

37A. No.

38Q. In your opinion, should a mineral supplement contain a set minimum of each mineral it purports to contain?

38A. Yes.

39Q. In your opinion, should a mineral supplement contain a set minimum of each mineral it purports to contain?

39A. Yes, because the minimum figure should be large enough to make a significant nutritional contribution.

40Q In your opinion, should vitamin and mineral supplements be available to the American public for routine use?

40A. Yes.

41Q. Your attention is directed to a statement contained in subparagraph (f) of Section 80.1 of Hearing Examiner Exhibit 3, which statement would be required to appear on the labels of most vitamin and mineral supplements. In your opinion, is this statement reasonable and will it inform the consumer of the value of the supplement?

41A. { In my opinion, it is not reasonable. The first sentence in the proposed statement states, "Vitamins and minerals are supplied in abundant amounts by commonly available foods." This statement is simply not true. The iron intake from the available food supply is marginal for many menstruating women. Further, based on my personal experience, even though nutrients may be available, many people do not eat food in the proper amounts and varieties to obtain adequate nutritional status. Finally, I believe it is undesirable to create an implication that every individual is getting all the nutrients he needs from his ordinary food supply. The second sentence states that... "except for a person with a special medical need, there is no scientific basis for recommending routine use of dietary supplements." This sentence is unsatisfactory in that it does not

1 again the evidence which I learned from nutritionists and
2 doctors is to the effect --

3 MR. KLEINFELD: I object to that.

4 EXAMINER HARRIS: Sustained.

5 Just give us the charge brought.

6 THE WITNESS: All right. The charge brought was that
7 the levels of one or five milligrams of potassium exaggerates the
8 value of the product since such a quantity is of no significance
9 to the diet.

10 EXAMINER HARRIS: Are there any specific proceedings
11 you can point us to?

12 THE WITNESS: The Vitasafe case, again, related to that
13 charge. It has also been brought in several other cases.

14 EXAMINER HARRIS: Do they come to mind?

15 THE WITNESS: I don't believe I could name another at
16 the moment, no.

17 BY MR. REILLY:

18 Q Are you familiar with the product Rose Hips?

19 A Yes. I have read a great deal about Rose Hips in
20 the literature.

21 EXAMINER HARRIS: Did you say Rose Hips?

22 MR. REILLY: Rose Hips, yes.

23 BY MR. REILLY:

24 Q Perhaps you could tell us what Rose Hips are?

25 A The rose is quite closely related to the apple in

1 for building bone, muscle and teeth, aid vitality, and poor
2 teeth, pasty complexion, and a number of other claims.

3 The soybean lecithin was described as a nerve and
4 brain food.

5 The wheatgerm oil was represented to be for weak-
6 ness, partial paralysis, sterility, disturbances during
7 pregnancy, and impaired mentality.

8 The Vitamin B Complex food supplement was for in-
9 digestion, poor appetite, fatigue, lack of energy, no pep,
10 nervousness, and so forth.

11 There were other charges concerning the mineral
12 capsules, that they were represented to contain all principal
13 minerals needed in the body, and the amount supplied was not
14 adequate to answer that description.

15 Incidentally, this Notice of Judgment No. is a Food
16 Notice of Judgment.

17 MR. KLEINFELD: I thank the witness for telling
18 us this at this time -- in this one instance.

19 MR. LAND: What number is that?

20 EXAMINER HARRIS: What number is the Notice of
21 Judgment?

22 THE WITNESS: 7924.

23 BY MR. REILLY:

24 Q. Can you recall the disposition of that case?

25 A. There was no claim entered and the product was

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that portion of that section, which establishes units suitable for and practicable of consumption in one day as the basis of a definition and standard of fair dealing for dietary supplements.

Have you reviewed that section, sir?

A. Yes, sir.

Q. Is it medically and pharmacologically reasonable that this definition is based on "units suitable for and applicable of consumption in one day"?

A. It is.

Q. Why is that a reasonable basis, Doctor?

A. Simply because the basis for a requirement of a material such as a vitamin is one which is over a given period. You could not take an ample amount for a month, or a week, for example. This is a manner in which a substance absorbed at the rate those are, utilized at a relative constant rate, as they are, this would be the scientific and medical method of administering such substances.

Q. Referring to the tables contained in Part 80.1(b) of the stayed regulations, Doctor, first from a qualitative point of view, is it reasonable that a dietary supplement contain these vitamins and mineral ingredients on the mandatory operational basis established therein?

MR. LAND: Objection, Your Honor. There are too many questions set forth in that.

1 BY MR. ANDERSON:

2 Q Does the fact that this product contains, purports to
3 contain, one thousand percent of the MDR for vitamin B₁ and
4 purports to contain 16 percent of the MDR of calcium affect
5 your evaluation or your opinion of this product?

6 A Yes. It leads me to the conclusion as to its
7 irrationality that I mentioned before. Why add 16 percent of
8 one thing? You are trying to give the impression, certainly,
9 it seems to me -- it seems to me this is aimed to give the
10 impression that it cures what ails you. And 16 percent of one,
11 only, and 10 times of another, I consider rather a ridiculous
12 mixture.

13 Q I show you now Government Exhibit 610, marked P-89
14 for identification. I ask you that you briefly review that
15 exhibit.

16 I particularly direct your attention to the portion
17 of the exhibit appearing to the left, in which the nutrient
18 contents are listed on the basis of nine tablets. As a
19 pharmacologist and practicing physician, do you have an opinion
20 as to the quality of the art of medicine shown by prescription
21 in the form of nine tablets?

22 A It is terrible, as far as "art", there is no art there.

23 Q I now show you Government 613, Doctor, marked for
24 identification as P-92.

25 A May I make one other criticism of this particular

1 the menstrual cycle having ceased in old people they do not
2 bleed, and therefore need less, the female sexual difference
3 I mentioned earlier does not exist, and this I would say is a
4 very irrational concoction of materials.

5 Q Specifically referring to Monosodium L-glutamate,
6 to your knowledge does that substance play any significant role
7 in human nutrition?

8 A Oh, it plays a role. We all have glutamic acid. It
9 is one of the amino acids.

10 Q Is there a necessity to supplement the diet on
11 a regular basis with that substance?

12 A No.

13 Q A necessity to do so in the diet of elderly persons?

14 A No.

15 MR. ANDERSON: Mr. Examiner, a thought occurs to me.
16 Would you prefer I extract a copy of each of these exhibits as
17 the Doctor reviews them for Your Honor's perusal?

18 EXAMINER HARRIS: No, I am following you.

19 BY MR. ANDERSON:

20 Q I now show you Government Exhibit 623, marked P-102
21 for identification. I ask you that you review that exhibit
22 briefly, with particular attention to the listing of the level
23 or multiples of minimum daily requirements with respect to the
24 mineral content of that product as compared to the vitamin
25 content.

1 A This is "Vita-Zymes, A Balanced Vitamin-Mineral
2 Supplement with Added Enzymes. Directions: As a dietary
3 supplement and to aid digestion, one capsule three times daily."
4 The list of the substances it contains, it has two and a half
5 times the MDR of vitamin A, the same for vitamin D. Six times as
6 much thiamin as the MDR. Five times riboflavin. Pyridoxine,
7 it gets down to about one. B₁₂, ascorbic acid, about three
8 times. Niacinamide, again it drops to about what is needed.
9 It has vitamin E. It has some lemon bioflavonoids, which, as
10 I said before have no particular value. It has inositol, which
11 you do not know, and has L-lysine, which as far as I know has
12 no -- is of course available from every time you eat protein.

13 Q May I stop you there? I would like to ask you to
14 elucidate your comment on lysine. How much lysine do we
15 find in this preparation?

16 A Fifteen milligrams.

17 Q How much lysine is ordinarily necessary in the human
18 nutrition?

19 A Oh, it would go up to the ordinary protein require-
20 ment, which we estimate in terms of grams, and lysine -- if you
21 were deficient, or normally?

22 Q Normally.

23 A Oh, normally I imagine about 1,000 -- around a gram or
24 so, roughly.

25 Q One thousand milligrams?

1 A That is right. So this would be a trifling amount.
2 If you needed it it would be too little; if you didn't need it it
3 would be wasting a little bit.

4 Q Please continue.

5 A It has a lot of salts in there -- zinc, magnesium,
6 manganese; then it has some enzymes, proteolytic enzyme, nylase
7 enzyme, amylase, in parentheses, is what they mean, 90
8 milligrams, cellulolytic enzyme (cellulase), nine milligrams.
9 The only one who could use that cellulase would be a horse, if
10 we gave him enough, because we do not digest cellulose, and I
11 don't think it would help us unless we took a chew of hay.
12 The amount of these enzymes would do us no good at all assuming
13 you needed them. It is ridiculous.

14 Q Did you observe the percent of MDR listed with
15 respect to calcium and phosphorus in this preparation?

16 A Very low. Then, this is like the lysine. They are
17 thrown in to give an ingredient, but not enough if you need
18 them, and useless if you do not need them.

19 I would say again this is a very irrational and
20 unbalanced mixture, it would make no sense except the obvious
21 reason, if you really took the MDR for calcium and the others
22 the pill would be as big as my fist, and would not be salable.
23 So they include only small amounts of some of these which take
24 a big amount. You can put a thousand units of A or D, because
25 it doesn't take much, and you can still swallow it.

MICKELSON - ADDENDUM PAGE 53

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1 for identification.

2 (Government Exhibit 822 was
3 marked P-167 for identification.)

4 BY MR. ANDERSON:

5 Q I ask you to tell us what this exhibit is.

6 A A label entitled "Apricot-Plus. Contains apricot
7 power enhanced with lemon powder, unrefined sugar, honey and
8 dextrose. Each wafer also contains 3.0 milligrams of Vitamin
9 C."

10 Q Doctor, what is your opinion with respect to the in-
11 clusion of 3.0 milligrams of Vitamin C in a dietary supplement
12 tablet?

13 A This level of Vitamin C is so small that it would be
14 insignificant insofar as the daily nutritional intake is con-
15 cerned if the individual were taking one of these tablets a
16 day.

17 Q I now show you Government Exhibit 824, P-168 for
18 identification.

19 (Government Exhibit 824,
20 P-168 was marked for
21 identification.)

22 BY MR. ANDERSON:

23 Q I ask you to tell us what this is, Doctor.

24 A Another label, entitled "Enduracol, Wheat Germ Oil
25 Capsules."

(Government Exhibit 825,
marked P-169 for identifica-
tion.)

BY MR. ANDERSON:

Q I ask you to tell us what this is.

A This is a label entitled "Kor-Val, Gelatin 16
grams."

Q I direct your attention to the directions appearing
on the left of this label and ask if there is any indication
as to the use which is recommended for this product?

A "Directions: One or two capsules with water after
each meal."

This gelatin is a protein found in connective tissue. It
is a protein that contains primarily the amino acid glycine, an
amino acid which can be readily synthesized by the body, and
for this reason is not listed as an essential amino acid.

Gelatin is very deficient in many of the amino acids
required by the body.

The level of intake suggested, 12 grams, would be approxi-
mately three-fourths of a gram, and under these circumstances it
would provide only one hundredth of the recommended dietary
intake of protein for a normal adult.

Q In your opinion, Doctor, is gelatin an appropriate
substance for inclusion in a standard of identity for a
dietary supplement?

the amount of desiccated liver contained in each tablet?

A "Each tablet contains Desiccated Liver undefatted
7 1/2 grains."

Q In your opinion is the ingestion of 7 and 1/2 grains of desiccated livers in a preparation such as this nutritionally significant to a human being?

A The level is very small; it would amount to approximately 300 -- 450 milligrams, not even one-half a gram. There is no indication on here as to the amounts of nutrients that are purported -- that one frequently associates with liver, such as thiamin, riboflavin, and other nutrients, in this particular preparation. So it would be difficult to say whether it would provide an adequate amount of any of the vitamins.

As far as protein is concerned, again liver is a good dietary source of protein. But the level of half a gram per day would be very insignificant as far as nutritional requirements are concerned.

Q Would you recommend the inclusion of 7 and 1/2 grains of powdered desiccated liver as a quantitative and qualitative ingredient in a dietary supplement, Doctor?

A This --

EXAMINER HARRIS: Go ahead, Doctor. The objections have fallen by the wayside. You may answer.

THE WITNESS: This level of nutrient from the standpoint of vitamins would have to be -- the label would have to

EXAMINER HARRIS: Read the question, Miss Ring.

(Question read.)

EXAMINER HARRIS: Go ahead and tie it up, Mr. Anderson. I will overrule the objection, Mr. Land.

BY MR. ANDERSON:

Q Dr. Mickelson, with respect to the ingestion of 425 milligrams of protein would this be a significant amount of protein in human nutrition?

A No, sir. We have discussed this previously, when we indicated that approximately half a gram is a very small proportion of the total daily requirement.

Q Would you include half a gram of protein as a constituent of a dietary supplement?

A We would have difficulty in actually finding this if we were to carry out a balance study with normal human subjects. This is within the error or experimental analysis.

Q With respect to this statement on the label, Doctor,
are amino acids essential in human nutrition?

A Yes.

Q Are the amounts of amino acids which would be found in 425 milligrams of protein a significant amount of amino acids in human nutrition?

A If 425 milligrams were made up entirely of one essential amino acid this would constitute a significant amount.
But there is no protein made up of only one essential amino

1 Q Could you tell us, sir, what is the basis for
2 assigning maximum values for these five groups for all the
3 vitamins and all the minerals?

4 A The criterion, again, was the recommended dietary
5 allowance of the Food and Nutrition Board.

6 Q Are these the same values as are found at Section
7 125.1(b)?

8 A Yes.

9 Q What is the basis for assigning minimum values of
10 nutrients to be found in dietary supplements?

11 A The reason for setting minimum values is no more than
12 to allow latitude for a variety of amounts which may be useful
13 in dietary supplementation and as accessory clinical practice
14 in the use of dietary supplements.

15 Q What numerical value was assigned for minimum amounts
16 of vitamins and minerals?

17 A The numerical values assigned have been one-half
18 of the respective maximum amounts -- I am sorry. I want to
19 correct this.

20 The minimum amounts for the first four groups is
21 one-fourth of the maximum except in the case of the infant, in
22 which case it is one-half.

23 Just to go on, the purpose in setting a relatively
24 higher minimum for the infant is simply to afford this group an
25 additional protection which it needs inherent in the -- in its

1 capability of choice or use of a wide variety of foods.

2 Q You stated that with the exception of the infant the
3 figure is one-quarter of the maximum. Does this relate to one
4 grouping, specifically to the adult grouping?

5 A It relates to the four groupings.

6 Q I direct your attention to the column designated
7 "Minimum Amounts for Any Person Except an Infant."

8 A Yes. And, of course, I was incorrect in what I said.
9 As stated by the table, for vitamin A, for example, the minimum
10 amount which might be present in a dietary supplement is
11 1250 U.S.P. units for any of the first four groups.

12 Q Does that hold true for the minimum amounts of minerals
13 as well?

14 A Yes.

15 Q In reviewing this entire table I would like to call
16 your attention to these names under the table designation
17 "Vitamins and Minerals": Vitamin A, niacin or niacinamide,
18 vitamin E, and folic acid. Do these terms refer --

19 A I am sorry, can you start again?

20 Q Does vitamin A refer both to Vitamin A activity, or the
21 preformed vitamin, or precursor?

22 A It refers to vitamin A activity.

23 Q By niacin or niacinamide, do you refer to the generic
24 vitamin niacin?

25 A Yes.

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EXAMINER LARSEN: It implies it to him.

MR. ULLMAN: Just implies it to him?

EXAMINER LARSEN: That is all he said. That is all he said.

THE WITNESS: That is what I meant.

MR. REILLY: I would like to mark as P-120 Government Exhibit 973, entitled "Vitro-Tox No. 21, a natural food concentrate for use as a dietary supplement."

(P-120 Government Exhibit No. 973 was marked for identification.)

INDEX

BY MR. REILLY:

Q Doctor, is that a sensible formula for a dietary supplement?

A Well, it does contain appropriate amounts of several of the essential vitamins and minerals. It contains less than appropriate amounts of some others.

Q What are the ingredients of which it contains less than appropriate amounts?

A It contains only 12 percent of the minimum daily requirement as listed here of niacin; it contains only 36 percent of the minimum daily requirement for phosphorus; yet it contains more than twice that amount of calcium. For ascorbic acid it has 200 percent of the minimum daily requirement. These seem to be inconsistencies.

In addition this has biotin, choline, and inositol,

1 which I believe have no real advantage in a formula of this type

2 Q I call attention to a special feature of this supple-
3 ment. Its base is "Green Life," which is a dried extracted
4 juice of one or more cereal grasses. Is this an important
5 nutritional factor?

6 A I don't think there is any advantage in the process
7 of obtaining essential nutrients from cereal grasses or any
8 other natural source as compared with the same nutrients ob-
9 tained from the chemist's laboratory.

10 Q I direct your attention to the fact that 16 tablets
11 provide the amounts of B12 -- the amounts of the B12 that you
12 just mentioned. Is that a sensible method of administering a
13 dietary supplement?

14 A I don't believe so.

15 MR. BILLY: I would like to mark P-131 for identifica-
16 tion, which is Government Exhibit 933, entitled "Hyadec,
17 High Potency Vitamin Formula with Minerals."

18 (P-131 Government Exhibit No. 933
19 was marked for identification.)

INDEX

20 BY MR. BILLY:

21 Q I would like to show you the first page of this
22 exhibit, which is the label for Hyadec, and ask you whether
23 this is a sensible formula in terms of the vitamins contained
24 therein and the amounts thereof contained, as a dietary supplement.

25 A This contains more than the recommended daily

is6

supplied in abundant amounts by commonly available foods ---?"

Q That's correct.

A Yes. I agree with the first sentence. I think it is entirely accurate. I am not certain it is necessary.

Q The second sentence?

A The second sentence I must disagree with, "Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements."

My own experience leads me to believe there are many people, probably some in this room, who don't eat as well as they should, and who would be better off if they ate proper foods or took a multivitamin supplement.

Q Would you propose any revision to that second statement in order to make it scientifically accurate?

A No. I would personally delete the second sentence.

Q I direct attention to Section 80.1(g) and ask you to read that.

A Yes, sir.

Q Doctor, do you have an opinion as to whether the requirements of this paragraph are reasonable?

A Yes, I think so.

Q Specifically, is there any need to state the quantity of the vitamins or minerals supplied by the supplement, on the label?

A Yes.

NOTE:
Statement
read out by
Hodges

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1 Q Should this be in terms of a daily quantity?
2 A That is a convenient way to express it.
3 Q Is that a commonly used form?
4 A It is the universally accepted way.
5 Q Is there any need to specify on the label the
6 quantity of the dietary supplement to be taken daily and the
7 frequency of ingestion?

8 A Yes, indeed. In fact, I think there should be a
9 limitation on those vitamins that have -- those preparations
10 that contain fat soluble vitamins. There should be a caution
11 note, in my opinion, warning people against excessive use,
12 because those can be very harmful.

13 EXAMINER HARRIS: Vitamin A?

14 THE WITNESS: Vitamin A, Vitamin D; yes, sir.

15 BY MR. REILLY:

16 Q I call your attention to Paragraph (i) and Paragraph
17 (j) of Section 80.1, and I ask you whether those are reasonable
18 requirements for statements to be placed on the label of a
19 dietary supplement?

20 A I think Paragraph (i) is perfectly reasonable.
21 Paragraph (j), I agree with.

22 Q Do you believe that ^{the} percent of the amount of
23 alcohol should be made clear to all purchasers?

24 A Yes. This is not an unreasonable requirement.

25 Q Does this statement appear in dietary supplements?

1 and would offer it in evidence.

2 EXAMINER HARRIS: I hear no objection.

3 I will receive it.

4 (Exhibit P-651, was received
5 in evidence.)

6 MR. REILLY: I will supply five copies when they
7 come in. They are expected in a couple of days.

8 EXAMINER HARRIS: Would you furnish me with a
9 copy?

10 MR. REILLY: I will, yes.

11 BY MR. REILLY:

12 Q Are the Recommended Dietary Allowances, then,
13 Doctor, as published in 1968, which are encompassed in P-651,
14 are these adequate to cover the individual variations that
15 you just discussed before?

16 A Yes.

17 Q Now, I wish to direct attention to the minimum
18 amounts for any person except an infant, which is found in
19 the first column of Tables 1 and 2 of the Stayed Regulations
20 80.1(b).

21 In your opinion, are these minimum amounts scientifically
22 sound?

23 A Yes.

24 Q I would also call your attention to the Footnote to
25 Table 1 and Table 2, and ask you whether it is scientifically

A 201 Affidavit of Service by Mail
**COURT OF APPEALS
SECOND CIRCUIT**

LUTZ APPELLATE PRINTERS, INC.

**NATIONAL NUTRITIONAL FOODS ASSOCIATION,
NATIONAL ASSOCIATION OF PHARMACEUTICAL
MANUFACTURERS & SOLGAR CO., INC.,
Petitioners,**

- against -

**DONALD KENNEDY, Comm. of Food & Drugs
UNITED STATES DEPT OF HEALTH ED &
WELFARE, Food & Drug Adm.
Respondents.**

Index No.

Affidavit of Service by Mail

STATE OF NEW YORK, COUNTY OF

ss.:

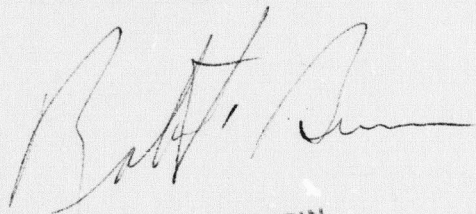
I, **Robert Martinez** being duly sworn,
depose and say that deponent is not a party to the action, is over 18 years of age and resides at
1165 Morris Avenue; Bronx, New York
That on the **2nd** day of **Mar** 1978, deponent served the annexed

Petition

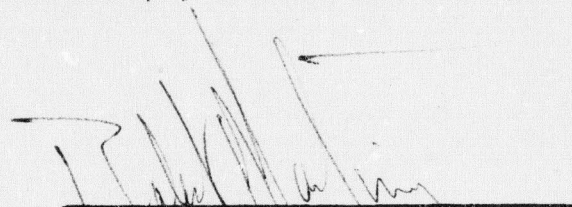
upon **1. Miles Robinson** attorney(s) for
2. Charles R. McConachie
1. 10120 Chapel Road; Potomac, Maryland
in this action, at **2. U.S. Dept of Justice; Washington, D.C.**

the address designated by said attorney(s) for that
purpose by depositing a true copy of same, enclosed in a postpaid properly addressed wrapper in a
Post Office Official Depository under the exclusive care and custody of the United States Post Office
Department, within the State of New York.

Sworn to before me, this **2**
day of **March,** 19 **78.**



ROBERT T. BRIN
NOTARY PUBLIC, State of New York
No. 31-0418950
Qualified in New York County
Commission Expires March 30, 1979


Robert Martinez